

US3092047 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3092047

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

[Participant ID](#)

US3092047

[mRNA-1273-P301 Completion Guidelines](#)

US3092047

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 00:29:02

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Date of Informed Consent (*dd MMM yyyy*) 6 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:29:02

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 00:29:03

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 00:29:02

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Condition	DMT2
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 00:29:02

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Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:29 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:29
Height (<i>xxx.x</i>)	169.2 cm
Weight (<i>xxx.x</i>)	142.8 kg
BMI (<i>xxx.x</i>)	49.88012 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 00:29:02

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Date of assessment (*dd MMM yyyy*) 06 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:29:03

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:29:03

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 142984

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒ No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☒ No ☐

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:25
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	17:48 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 17:48
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 6 AUG 2020

What was the treatment time? (00:00-23:59) 17:05 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 17:05

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	16:57 (24 HR)
Collection date and time (derived)	06 AUG 2020 16:57

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:55	06 AUG 2020 16:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

06 AUG 2020 17:36

PC Open Date & Time

06 AUG 2020 17:25

PC Close Date & Time

06 AUG 2020 19:55

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	07 AUG 2020 11:38
PC Open Date & Time	06 AUG 2020 20:50
PC Close Date & Time	07 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 AUG 2020 00:24

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 AUG 2020 14:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

09 AUG 2020 13:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

10 AUG 2020 21:34

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

11 AUG 2020 22:22

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 AUG 2020 21:11
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 8

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 AUG 2020 22:25

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 17:37

PC Open Date & Time

06 AUG 2020 17:25

PC Close Date & Time

06 AUG 2020 19:55

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 11:38

PC Open Date & Time

06 AUG 2020 20:50

PC Close Date & Time

07 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 00:24

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 14:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 13:25

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 13:15

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 22:22

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 21:12

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 17:36
PC Open Date & Time	06 AUG 2020 17:25
PC Close Date & Time	06 AUG 2020 19:55

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 11:39
PC Open Date & Time	06 AUG 2020 20:50
PC Close Date & Time	07 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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EAB) (1725)

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 00:25
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 14:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 13:25
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

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EAB) (1725)

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

		Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 21:35	
PC Open Date & Time	10 AUG 2020 12:00	
PC Close Date & Time	11 AUG 2020 11:59	

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:23
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 21:12
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 13 AUG 2020 22:25

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 14 AUG 2020 17:16

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 22:25
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 17:16
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3092047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 15:19
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 16:21
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3092047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 15:47 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 15:47

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3092047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

15:46 (24 HR)

Collection date and time (derived)

14 SEP 2020 15:46

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:41	14 SEP 2020 15:41
Nasopharyngeal Swab 2	No		

US3092047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

14 SEP 2020 16:17

PC Open Date & Time

14 SEP 2020 16:07

PC Close Date & Time

14 SEP 2020 18:37

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	14 SEP 2020 22:23
PC Open Date & Time	14 SEP 2020 19:32
PC Close Date & Time	15 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

16 SEP 2020 14:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

17 SEP 2020 16:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

19 SEP 2020 14:08

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

21 SEP 2020 00:18

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 16:17

PC Open Date & Time

14 SEP 2020 16:07

PC Close Date & Time

14 SEP 2020 18:37

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:23

PC Open Date & Time

14 SEP 2020 19:32

PC Close Date & Time

15 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 14:17

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 16:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 14:08

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 00:18

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 16:16
PC Open Date & Time	14 SEP 2020 16:07
PC Close Date & Time	14 SEP 2020 18:37

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 22:23
PC Open Date & Time	14 SEP 2020 19:32
PC Close Date & Time	15 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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EAB) (1725)

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 14:17
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 00:17
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3092047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 14:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

14:24 (24 HR)

Collection date and time (derived)

11 NOV 2020 14:24

US3092047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 64

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

06 OCT 2020 03:29:35

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 124

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

05 DEC 2020 00:26:44

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 DEC 2020 01:13:37

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

19 DEC 2020 13:21:15

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

26 DEC 2020 00:25:46

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 JAN 2021 21:08:30

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 JAN 2021 23:56:42

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 JAN 2021 21:46:23

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 FEB 2021 19:29:06

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 01:43:49
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 FEB 2021 09:29:41

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 FEB 2021 23:11:48

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 MAR 2021 10:25:30

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 MAR 2021 01:36:08

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 MAR 2021 01:05:24
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 APR 2021 00:15:46

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 460

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3092047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:06:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:11:59

US3092047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 FEB 2021

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments 1ST ATTEMPT MADE ON
02/08/21
If Contact Not Made, please provide Comments 2ND ATTEMPT MADE ON
02/09/21
3RD ATTEMPT MADE ON
02/10/21

US3092047

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3092047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3092047

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3092047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:22:02

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092047

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Date of Contact	10 AUG 2020
Time of Contact	00:00
Date and Time of Contact (derived)	10 AUG 2020 00:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Mar 2021 22:39:39

Generated On: 09 Jun 2021 15:06:27

Date of Visit	10 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	10 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3092047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092047

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 00:29:02

Generated On: 09 Jun 2021 15:06:27

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 AUG 2020

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID SICKD28

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 22:39:39

Generated On: 09 Jun 2021 15:06:27

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID UNBLND_DECIDE

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:06:27

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded?

Yes ☐

No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐

Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*)

Participant randomization assignment

mRNA-1273 ☐

Placebo ☐

Actual Dose 1

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Actual Dose 2

mRNA-1273 ☐

Placebo ☐

Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐

No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:06:27

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Visit Date	12 OCT 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:29:03

Generated On: 09 Jun 2021 15:06:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3092047

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	MUSCULOSKELETAL CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	BODY ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

AEID	USA-US086-2021-MRNA-1273-P30 1000013
Adverse event	COPD EXACERBATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	18 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

SUBJECT WAS SCHEDULED FOR
AN APPOINTMENT ON
15-MAR-2021.SHE CALLED AND
STATED THAT SHE MISSED THE
APPOINTMENT BECAUSE SHE
HOSPITALIZED ON 14-MAR-2021
DUE TO COPD.NO OTHER
INFORMATION WAS PROVIDED.
SUBJECT HAS BEEN
CONTACTED FOR ADDITIONAL
INFORMATION BUT SITE HAS
NOT BEEN ABLE TO SPEAK
WITH HER. SAE WILL BE
UPDATED WHEN
INFORMATION IS AVAILABLE

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

AEID

Adverse event

CHRONIC OBSTRUCTIVE
PULMONARY DISEASE (COPD)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

UN JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:27

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:06:27

Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:28:51

Generated On: 09 Jun 2021 15:06:27

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	NOVOLOG INSULIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Start date completely unknown		True
Ongoing?		Yes <input checked="" type="radio"/>
		No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived) <input type="text"/>		
<hr/>		
Interval Dosage Unit Number (derived) <input type="text"/>		
<hr/>		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	LANTUS INSULIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Start date completely unknown		True <input type="checkbox"/>
Ongoing?		Yes <input checked="" type="radio"/>
		No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived) <input type="text"/>		
<hr/>		
Interval Dosage Unit Number (derived) <input type="text"/>		
<hr/>		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	ALBUTEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	90
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
<hr/>		
Start date (dd MMM yyyy) <hr/>		
<hr/>		
Start date completely unknown		True
<hr/>		
Ongoing?		Yes <input checked="" type="radio"/>
		No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
<hr/>		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
<hr/>		
Interval Dosage Unit Number (derived)		<hr/>
<hr/>		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>
<hr/>		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Indication	FLU PREVENTION
Dose per administration	UNK
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	ONCE A YEAR
	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	TYLENOL
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CHEST PAIN
Dose per administration	UNK
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	ROBAXIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHRONIC LOW BACK PAIN
Dose per administration	750
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	TORSEMIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COPD EXARCEBATION
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Mar 2021 18:18:55

Generated On: 09 Jun 2021 15:06:27

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:06:27

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3092047

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:06:27

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

SAEID	USA-US086-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75033
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

SAEID	USA-US086-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75033
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/MAR/2021 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

SAEID	USA-US086-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75033
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:22:01

Generated On: 09 Jun 2021 15:06:27

SAEID	USA-US086-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75033
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 08:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3092047 (Prod: Global Medical Research - M3 Wake Research)

US3092047

Form: Participant Creation

Generated On: 09 Jun 2021 15:06:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'US3092047'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:13

US3092047

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	06 Aug 2020 22:10:29

US3092047

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:14

US3092047

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	06 Aug 2020 22:10:29

US3092047

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'SCRN'	System	06 Aug 2020 22:10:29

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered (b) (6) 1973'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:15

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '47'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'YEARS'	System	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered '47'	System	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Female (F)'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'I'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:06:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:18

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '6 Aug 2020'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'Aug 2020'	System	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered '2020'	System	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Amendment 1 (1)'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:43

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:14

US3092047

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:06:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'I'	System	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:06:27

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:06:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:17

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:45:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:45:15
Data point term sent to Coder	System	17 Aug 2020 19:43:48
User entered 'DMT2'	Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'UN UNK 2002'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'Jan 2002'	System	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered '2002'	System	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:06:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	17 Aug 2020 19:43:39

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:45:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:45:16
Data point term sent to Coder	System	17 Aug 2020 19:44:50
User entered 'MODERATE ASTHMA'	Shraddha Dubal (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'UN UNK 1994'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'Jan 1994'	System	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered '1994'	System	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:06:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	17 Aug 2020 19:44:17

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 15:06:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 15:06:43
Data point term sent to Coder	System	16 Nov 2020 15:05:52
User entered 'POST-MENOPAUSAL' reason for change: Data Entry Error	Catina Adams (b) (4)	16 Nov 2020 15:05:05
Data point term sent to Coder	System	16 Nov 2020 15:03:51
User entered 'Post-menopausal'	Catina Adams (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'I'	Catina Adams (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:32:31
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	16 Nov 2020 15:04:20
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:04:20
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	16 Nov 2020 15:02:59
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per DM CLR: Please review the stop date of this MH condition as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 08:50:53
Query 'Per DM CLR: Please review the stop date of this MH condition as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'corrected per query' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:32:40
User entered '0' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:32:31
User opened query 'Per DM CLR: Please review the stop date of this MH condition as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:51:34
User entered '1'	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:06:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered empty.	System	16 Nov 2020 15:02:59

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '16:29'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered '06 Aug 2020 16:29'	System	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '169.2' cm	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00
DataPoint set to visible.	(b) (4) System	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '142.8' kg	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00
DataPoint set to visible.	(b) (4) System	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
Amendment Manager: User entered '49.88012'	System	16 Sep 2020 23:46:37
User entered '49.9'	System	17 Aug 2020 19:45:00
DataPoint set to visible.	System	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'kg/m2'	System	17 Aug 2020 19:45:00
DataPoint set to visible.	System	06 Aug 2020 22:12:49

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 05:42:18
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	21 Oct 2020 02:09:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	21 Oct 2020 02:09:23
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 17:37:15
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 17:52:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	18 Aug 2020 17:52:45
User entered '37.2' C reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 19:45:00
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty; reason for change Data Entry Error	(b) (4) Vicki Martinez (b) (4)	21 Oct 2020 02:09:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	18 Aug 2020 17:52:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 17:52:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 19:45:00
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 02:09:23
User closed query 'Data is required. Please provide.' (Site from System).	Vicki Martinez (b) (4)	18 Aug 2020 17:52:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	18 Aug 2020 17:52:45
User entered '85' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:45:00
User entered empty.	System	17 Aug 2020 19:45:00
	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00
	(b) (4)	

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'bpm'	System	18 Aug 2020 17:52:45
User entered empty.	System	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 02:09:23
User closed query 'Data is required. Please provide.' (Site from System).	Vicki Martinez (b) (4)	18 Aug 2020 17:52:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	18 Aug 2020 17:52:45
User entered '16' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:45:00
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'breaths/min'	System	18 Aug 2020 17:52:45
User entered empty.	System	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	Vicki Martinez (b) (4)	21 Oct 2020 02:09:23
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	
User entered '147' reason for change: Data Entry Error	System	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 17:52:45
User entered empty.	Shraddha Dubal (b) (4)	18 Aug 2020 17:52:45
	(b) (4)	
	System	17 Aug 2020 19:45:00
	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00
	(b) (4)	

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'mmHg'	System	18 Aug 2020 17:52:45
User entered empty.	System	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Oct 2020 02:09:23
User closed query 'Data is required. Please provide.' (Site from System).	Vicki Martinez (b) (4)	18 Aug 2020 17:52:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	(b) (4)	18 Aug 2020 17:52:45
User entered '66' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 19:45:00
User entered empty.	System	17 Aug 2020 19:45:00
	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:00
	(b) (4)	

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User entered 'mmHg'	System	18 Aug 2020 17:52:45
User entered empty.	System	17 Aug 2020 19:45:00

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35

US3092047

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35

US3092047

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:11

US3092047

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:15:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:13:18
User entered '06 Aug 2020'	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:11
	(b) (4)	

US3092047

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:51

US3092047

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:51

US3092047

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:55:07
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:00:50
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:42:10
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	18 Aug 2020 17:51:47
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	18 Aug 2020 17:51:47
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	18 Aug 2020 17:51:19
User opened query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	18 Aug 2020 17:51:19
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	18 Aug 2020 17:51:19
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	18 Aug 2020 17:51:19
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:51:19

US3092047

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	17 Aug 2020 19:45:51
User opened query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		17 Aug 2020 19:45:51
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:51

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty; reason for change Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:51:47
	(b) (4)	
User entered 'BILATERAL TUBAL LIGATION'	Shraddha Dubal (b) (4)	17 Aug 2020 19:45:51
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:51

US3092047

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0' reason for change: Data Entry Error	(b) (4) Shraddha Dubal (b) (4)	18 Aug 2020 17:51:47
User entered '1'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:45:51

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:51

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:06:27

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'I'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:45:51

US3092047

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

US3092047

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

US3092047

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

US3092047

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'I'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

US3092047

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:06:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:14:09

US3092047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per GCL Lab Recon: GCL has a SARS_CoV-2 sample with date of 10AUG2020; however, there is no Illness Visit recorded. Please reconcile or clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:59:09
Query 'Per GCL Lab Recon: GCL has a SARS_CoV-2 sample with date of 10AUG2020; however, there is no Illness Visit recorded. Please reconcile or clarify ' answered with 'illness visit has been entered' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:33:18
User opened query 'Per GCL Lab Recon: GCL has a SARS_CoV-2 sample with date of 10AUG2020; however, there is no Illness Visit recorded. Please reconcile or clarify ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:25:30
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	06 Aug 2020 22:14:25

US3092047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '6 Aug 2020'	(b) (4) Vicki Martinez (b) (4) (b) (4)	06 Aug 2020 22:14:25

US3092047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4)	06 Aug 2020 22:14:25

US3092047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'VISIT1'	System	06 Aug 2020 22:14:25

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:16

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:44:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:44:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:59:16
User entered '142984' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:59:16

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:15:40

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	Vicki Martinez (b) (4)	06 Aug 2020 22:15:40

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	06 Aug 2020 22:15:40

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:15:40

US3092047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:06:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	06 Aug 2020 22:15:40

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 06:18:39
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 04:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:57
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 17:38:21
User entered '169.2' cm reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:53:43
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:57
User entered '142.8' kg reason for change: Data Entry Error	Vicki Martinez (b) (4)	23 Oct 2020 03:59:57
User entered empty.	(b) (4)	23 Oct 2020 03:59:57
	Shraddha Dubal (b) (4)	18 Aug 2020 17:53:43
	(b) (4)	18 Aug 2020 17:53:43
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 06:18:39
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 04:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:57
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 17:38:21
User entered '169.2' cm reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:53:43
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:57
User entered '142.8' kg reason for change: Data Entry Error	Vicki Martinez (b) (4)	18 Aug 2020 17:53:43
User entered empty.	(b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Pre-Dose (PREDOSE)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	18 Aug 2020 17:55:19
User entered '16:25' reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:55:19
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:46:46
User entered '17:48'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '06 Aug 2020 16:25'	System	18 Aug 2020 17:55:19
User entered '06 Aug 2020 17:48'	System	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '37.2' C reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:55:19
User entered '97.6' F	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Oral (Oral)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '85' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:55:19
User entered '86'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'bpm'	System	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:55:19
User entered '18'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'breaths/min'	System	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '147' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:55:19
User entered '148'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	17 Aug 2020 19:46:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '66' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:55:19
User entered '84'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	17 Aug 2020 19:46:46

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 06:18:39
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' answered with 'ND' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 04:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Vicki Martinez (b) (4) (b) (4)	23 Oct 2020 03:59:57
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 17:38:21
User entered '169.2' cm reason for change: Data Entry Error	Shraddha Dubal (b) (4) (b) (4)	18 Aug 2020 17:53:43
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:46:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:06:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Oct 2020 03:59:57
User entered '142.8' kg reason for change: Data Entry Error	Vicki Martinez (b) (4)	23 Oct 2020 03:59:57
User entered empty.	(b) (4)	23 Oct 2020 03:59:57
	Shraddha Dubal (b) (4)	18 Aug 2020 17:53:43
	(b) (4)	18 Aug 2020 17:53:43
	Shraddha Dubal (b) (4)	17 Aug 2020 19:46:46
	(b) (4)	17 Aug 2020 19:46:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Post-Dose (POSTDOSE)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:47:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 02:43:59
User entered '17:48' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	18 Aug 2020 17:55:19
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:47:58
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:47:58
User entered '16:29'	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '06 Aug 2020 17:48'	System	18 Aug 2020 17:57:25
User entered '06 Aug 2020 16:29'	System	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '97.6' F reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User entered '37.2' C	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Oral (Oral)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '86' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User entered '85'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'bpm'	System	17 Aug 2020 19:47:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '18' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User entered '16'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'breaths/min'	System	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '148' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User entered '147'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '84' reason for change: Data Entry Error	(b) (4)	
	Shraddha Dubal (b) (4)	18 Aug 2020 17:57:25
User entered '66'	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:47:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	17 Aug 2020 19:47:58

US3092047

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:48:11

US3092047

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:48:11

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '6 Aug 2020'	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '17:05'	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered '6 Aug 2020 17:05'	System	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Left Arm (LEFT ARM)'	Vicki Martinez (b) (4)	06 Aug 2020 22:16:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'ONCE'	System	06 Aug 2020 22:16:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 22:16:24

US3092047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	18 Aug 2020 14:40:22

US3092047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	Vicki Martinez (b) (4)	18 Aug 2020 14:40:22

US3092047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 14:27:32
User entered '16:57' reason for change: Data Entry Error	System	16 Nov 2020 14:27:32
User opened query 'Data is required. Please provide.' (Site from System).	Catina Adams (b) (4)	16 Nov 2020 14:27:32
User entered empty.	(b) (4)	18 Aug 2020 14:40:22
	Vicki Martinez (b) (4)	18 Aug 2020 14:40:22
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered '06 Aug 2020 16:57'	System	16 Nov 2020 14:27:32
User entered empty.	System	18 Aug 2020 14:40:22

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '06 Aug 2020'	Vicki Martinez (b) (4)	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Vicki Martinez (b) (4) (b) (4)	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 18:00:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 18:00:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 18:00:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 14:40:33
User entered empty.	System	18 Aug 2020 14:40:33
	Vicki Martinez (b) (4)	18 Aug 2020 14:40:33
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 14:28:26
	System	16 Nov 2020 14:28:26
User entered '16:55' reason for change: Data Entry Error	Catina Adams (b) (4)	16 Nov 2020 14:28:26
	(b) (4)	
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Aug 2020 18:00:11
User entered empty.	Vicki Martinez (b) (4)	18 Aug 2020 14:40:33
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered '06 Aug 2020 16:55'	System	16 Nov 2020 14:28:26
User entered empty.	System	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Vicki Martinez (b) (4) (b) (4)	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 18:00:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 18:00:11
User entered 'No (N)' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	18 Aug 2020 18:00:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Aug 2020 14:40:33
User entered empty.	System	18 Aug 2020 14:40:33
	Vicki Martinez (b) (4)	18 Aug 2020 14:40:33
	(b) (4)	

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered empty.	System	18 Aug 2020 14:40:33

US3092047

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	06 Aug 2020 22:16:32

US3092047

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	06 Aug 2020 22:16:32

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '9f7abf91-e4fa-4589-8aac-a35edc360bc5'	System	06 Aug 2020 22:36:51
User entered 'Yes (Y)'	System	06 Aug 2020 22:36:51

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:38', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '9f7abf91-e4fa-4589-8aac-a35edc360bc5' User entered '97.4'	System	06 Aug 2020 22:36:51
	System	06 Aug 2020 22:36:51

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '9f7abf91-e4fa-4589-8aac-a35edc360bc5'	System	06 Aug 2020 22:36:51
User entered 'No (N)'	System	06 Aug 2020 22:36:51

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '9f7abf91-e4fa-4589-8aac-a35edc360bc5'	System	06 Aug 2020 22:36:51
User entered '06 Aug 2020 17:36'	System	06 Aug 2020 22:36:51

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 17:25'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 19:55'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:37:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '54d1a5c8-c12e-433f-bd77-3fc4faad76cd'	System	07 Aug 2020 16:38:19
User entered 'Yes (Y)'	System	07 Aug 2020 16:38:19

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:04', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '54d1a5c8-c12e-433f-bd77-3fc4faad76cd' User entered '97.5'	System	07 Aug 2020 16:38:19
	System	07 Aug 2020 16:38:19

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:09', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '54d1a5c8-c12e-433f-bd77-3fc4faad76cd'	System	07 Aug 2020 16:38:19
User entered 'No (N)'	System	07 Aug 2020 16:38:19

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:12', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '54d1a5c8-c12e-433f-bd77-3fc4faad76cd' User entered '07 Aug 2020 11:38'	System	07 Aug 2020 16:38:19
	System	07 Aug 2020 16:38:19

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 20:50'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 2'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:23:50', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '44db47a5-4dd0-4fb3-93fc-31830dd998d8'	System	08 Aug 2020 05:24:16
User entered 'Yes (Y)'	System	08 Aug 2020 05:24:16

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '44db47a5-4dd0-4fb3-93fc-31830dd998d8'	System	08 Aug 2020 05:24:16
User entered '98.6'	System	08 Aug 2020 05:24:16

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '44db47a5-4dd0-4fb3-93fc-31830dd998d8'	System	08 Aug 2020 05:24:16
User entered 'No (N)'	System	08 Aug 2020 05:24:16

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:12', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '44db47a5-4dd0-4fb3-93fc-31830dd998d8'	System	08 Aug 2020 05:24:16
User entered '08 Aug 2020 00:24'	System	08 Aug 2020 05:24:16

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 3'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4668a651-eb3c-4be9-a74b-6ce2a6f4ac91'	System	08 Aug 2020 19:03:46
User entered 'Yes (Y)'	System	08 Aug 2020 19:03:46

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4668a651-eb3c-4be9-a74b-6ce2a6f4ac91'	System	08 Aug 2020 19:03:46
User entered '97.4'	System	08 Aug 2020 19:03:46

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4668a651-eb3c-4be9-a74b-6ce2a6f4ac91'	System	08 Aug 2020 19:03:46
User entered 'No (N)'	System	08 Aug 2020 19:03:46

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4668a651-eb3c-4be9-a74b-6ce2a6f4ac91'	System	08 Aug 2020 19:03:46
User entered '08 Aug 2020 14:03'	System	08 Aug 2020 19:03:46

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 4'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:24:31', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4eda4a48-90a4-445a-9f85-bb250e33c043'	System	09 Aug 2020 18:24:55
User entered 'Yes (Y)'	System	09 Aug 2020 18:24:55

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:24:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4eda4a48-90a4-445a-9f85-bb250e33c043'	System	09 Aug 2020 18:24:55
User entered '98.4'	System	09 Aug 2020 18:24:55

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:24:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4eda4a48-90a4-445a-9f85-bb250e33c043'	System	09 Aug 2020 18:24:55
User entered 'No (N)'	System	09 Aug 2020 18:24:55

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:24:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4eda4a48-90a4-445a-9f85-bb250e33c043'	System	09 Aug 2020 18:24:55
User entered '09 Aug 2020 13:24'	System	09 Aug 2020 18:24:55

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 5'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:34:20', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c4a7cce1-349b-4d95-ba01-cefc0c2c0b98'	System	11 Aug 2020 02:34:41
User entered 'Yes (Y)'	System	11 Aug 2020 02:34:41

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:34:28', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c4a7cce1-349b-4d95-ba01-cefc0c2c0b98'	System	11 Aug 2020 02:34:41
User entered '98.2'	System	11 Aug 2020 02:34:41

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:34:33', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c4a7cce1-349b-4d95-ba01-cefc0c2c0b98'	System	11 Aug 2020 02:34:41
User entered 'No (N)'	System	11 Aug 2020 02:34:41

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:34:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c4a7cce1-349b-4d95-ba01-cefc0c2c0b98'	System	11 Aug 2020 02:34:41
User entered '10 Aug 2020 21:34'	System	11 Aug 2020 02:34:41

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 6'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'a18b7348-c125-4656-8344-14da65a3d60c'	System	12 Aug 2020 03:22:22
User entered 'Yes (Y)'	System	12 Aug 2020 03:22:22

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:11', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'a18b7348-c125-4656-8344-14da65a3d60c'	System	12 Aug 2020 03:22:22
User entered '98.4'	System	12 Aug 2020 03:22:22

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'a18b7348-c125-4656-8344-14da65a3d60c'	System	12 Aug 2020 03:22:22
User entered 'No (N)'	System	12 Aug 2020 03:22:22

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'a18b7348-c125-4656-8344-14da65a3d60c'	System	12 Aug 2020 03:22:22
User entered '11 Aug 2020 22:22'	System	12 Aug 2020 03:22:22

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 7'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a'	System	13 Aug 2020 02:11:59
User entered 'Yes (Y)'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a' User entered '98.4'	System	13 Aug 2020 02:11:59
	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a'	System	13 Aug 2020 02:11:59
User entered 'Yes (Y)'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took tylenol' (Site from System).		17 Nov 2020 07:48:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took tylenol' (Site from System).	Catina Adams (b) (4)	16 Nov 2020 15:23:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Aug 2020 02:11:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a'	System	13 Aug 2020 02:11:59
User entered '1'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a' User entered '0'	System	13 Aug 2020 02:11:59
	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:53', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0f57d06b-d4b4-4eb0-a2d8-4adb76216d8a'	System	13 Aug 2020 02:11:59
User entered '12 Aug 2020 21:11'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	13 Aug 2020 02:11:59
User entered 'Day 8'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:24:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7a3cb76c-8933-41d6-be05-e1337ac34d6b'	System	14 Aug 2020 03:25:27
User entered 'Yes (Y)'	System	14 Aug 2020 03:25:27

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:24:51', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7a3cb76c-8933-41d6-be05-e1337ac34d6b' User entered '97.4'	System	14 Aug 2020 03:25:27
	System	14 Aug 2020 03:25:27

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:24:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7a3cb76c-8933-41d6-be05-e1337ac34d6b'	System	14 Aug 2020 03:25:27
User entered 'No (N)'	System	14 Aug 2020 03:25:27

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:25:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7a3cb76c-8933-41d6-be05-e1337ac34d6b'	System	14 Aug 2020 03:25:27
User entered '13 Aug 2020 22:25'	System	14 Aug 2020 03:25:27

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:53', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '703ebe78-14b6-4cd4-94a4-5ee4d2cddb9f'	System	06 Aug 2020 22:37:14
User entered 'None (1)'	System	06 Aug 2020 22:37:14

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '703ebe78-14b6-4cd4-94a4-5ee4d2cddb9f'	System	06 Aug 2020 22:37:14
User entered 'No (N)'	System	06 Aug 2020 22:37:14

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:37:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '703ebe78-14b6-4cd4-94a4-5ee4d2cddb9f'	System	06 Aug 2020 22:37:14
User entered 'No (N)'	System	06 Aug 2020 22:37:14

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:37:04', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '703ebe78-14b6-4cd4-94a4-5ee4d2cddb9f'	System	06 Aug 2020 22:37:14
User entered 'None (1)'	System	06 Aug 2020 22:37:14

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:37:07', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '703ebe78-14b6-4cd4-94a4-5ee4d2cddb9f'	System	06 Aug 2020 22:37:14
User entered '06 Aug 2020 17:37'	System	06 Aug 2020 22:37:14

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 17:25'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 19:55'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:25', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '235545d0-2274-4269-aa19-3ccef233d848'	System	07 Aug 2020 16:38:49
User entered 'None (1)'	System	07 Aug 2020 16:38:49

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '235545d0-2274-4269-aa19-3ccef233d848'	System	07 Aug 2020 16:38:49
User entered 'No (N)'	System	07 Aug 2020 16:38:49

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '235545d0-2274-4269-aa19-3ccef233d848'	System	07 Aug 2020 16:38:49
User entered 'No (N)'	System	07 Aug 2020 16:38:49

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '235545d0-2274-4269-aa19-3ccef233d848'	System	07 Aug 2020 16:38:49
User entered 'None (1)'	System	07 Aug 2020 16:38:49

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:43', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '235545d0-2274-4269-aa19-3ccef233d848'	System	07 Aug 2020 16:38:49
User entered '07 Aug 2020 11:38'	System	07 Aug 2020 16:38:49

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 20:50'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 2'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:20', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0bad7dee-7cf8-4c64-8431-8380d33c113c'	System	08 Aug 2020 05:24:53
User entered 'None (1)'	System	08 Aug 2020 05:24:53

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:24', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0bad7dee-7cf8-4c64-8431-8380d33c113c'	System	08 Aug 2020 05:24:53
User entered 'No (N)'	System	08 Aug 2020 05:24:53

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:27', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0bad7dee-7cf8-4c64-8431-8380d33c113c'	System	08 Aug 2020 05:24:53
User entered 'No (N)'	System	08 Aug 2020 05:24:53

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:43', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0bad7dee-7cf8-4c64-8431-8380d33c113c'	System	08 Aug 2020 05:24:53
User entered 'None (1)'	System	08 Aug 2020 05:24:53

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0bad7dee-7cf8-4c64-8431-8380d33c113c'	System	08 Aug 2020 05:24:53
User entered '08 Aug 2020 00:24'	System	08 Aug 2020 05:24:53

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 3'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'e1a2951c-3453-4e83-8d04-11bc4cb505f3'	System	08 Aug 2020 19:04:01
User entered 'None (1)'	System	08 Aug 2020 19:04:01

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'e1a2951c-3453-4e83-8d04-11bc4cb505f3'	System	08 Aug 2020 19:04:01
User entered 'No (N)'	System	08 Aug 2020 19:04:01

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:52', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'e1a2951c-3453-4e83-8d04-11bc4cb505f3'	System	08 Aug 2020 19:04:01
User entered 'No (N)'	System	08 Aug 2020 19:04:01

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'e1a2951c-3453-4e83-8d04-11bc4cb505f3'	System	08 Aug 2020 19:04:01
User entered 'None (1)'	System	08 Aug 2020 19:04:01

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:03:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'e1a2951c-3453-4e83-8d04-11bc4cb505f3'	System	08 Aug 2020 19:04:01
User entered '08 Aug 2020 14:03'	System	08 Aug 2020 19:04:01

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 4'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:24:57', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '05ab8ade-2b83-404e-8fb8-e3b7005951d3'	System	09 Aug 2020 18:25:23
User entered 'None (1)'	System	09 Aug 2020 18:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:01', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '05ab8ade-2b83-404e-8fb8-e3b7005951d3'	System	09 Aug 2020 18:25:23
User entered 'No (N)'	System	09 Aug 2020 18:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '05ab8ade-2b83-404e-8fb8-e3b7005951d3'	System	09 Aug 2020 18:25:23
User entered 'No (N)'	System	09 Aug 2020 18:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '05ab8ade-2b83-404e-8fb8-e3b7005951d3'	System	09 Aug 2020 18:25:23
User entered 'None (1)'	System	09 Aug 2020 18:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '05ab8ade-2b83-404e-8fb8-e3b7005951d3'	System	09 Aug 2020 18:25:23
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 18:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 5'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T13:15:19', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6fec9ceb-e365-4c7d-8a29-f38db7fe0ea8'	System	10 Aug 2020 18:15:40
User entered 'None (1)'	System	10 Aug 2020 18:15:40

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T13:15:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6fec9ceb-e365-4c7d-8a29-f38db7fe0ea8'	System	10 Aug 2020 18:15:40
User entered 'No (N)'	System	10 Aug 2020 18:15:40

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T13:15:25', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6fec9ceb-e365-4c7d-8a29-f38db7fe0ea8'	System	10 Aug 2020 18:15:40
User entered 'No (N)'	System	10 Aug 2020 18:15:40

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T13:15:33', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6fec9ceb-e365-4c7d-8a29-f38db7fe0ea8'	System	10 Aug 2020 18:15:40
User entered 'None (1)'	System	10 Aug 2020 18:15:40

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T13:15:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6fec9ceb-e365-4c7d-8a29-f38db7fe0ea8'	System	10 Aug 2020 18:15:40
User entered '10 Aug 2020 13:15'	System	10 Aug 2020 18:15:40

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 6'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6d8273a0-e1b5-4b7d-803f-c8e586b892c9'	System	12 Aug 2020 03:22:37
User entered 'None (1)'	System	12 Aug 2020 03:22:37

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:24', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6d8273a0-e1b5-4b7d-803f-c8e586b892c9'	System	12 Aug 2020 03:22:37
User entered 'No (N)'	System	12 Aug 2020 03:22:37

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:27', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6d8273a0-e1b5-4b7d-803f-c8e586b892c9'	System	12 Aug 2020 03:22:37
User entered 'No (N)'	System	12 Aug 2020 03:22:37

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:29', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6d8273a0-e1b5-4b7d-803f-c8e586b892c9'	System	12 Aug 2020 03:22:37
User entered 'None (1)'	System	12 Aug 2020 03:22:37

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6d8273a0-e1b5-4b7d-803f-c8e586b892c9'	System	12 Aug 2020 03:22:37
User entered '11 Aug 2020 22:22'	System	12 Aug 2020 03:22:37

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 7'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:57', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '90d80b59-b3b7-4a71-bf9d-41d8b3f326a6'	System	13 Aug 2020 02:12:15
User entered 'None (1)'	System	13 Aug 2020 02:12:15

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:11:59', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '90d80b59-b3b7-4a71-bf9d-41d8b3f326a6'	System	13 Aug 2020 02:12:15
User entered 'No (N)'	System	13 Aug 2020 02:12:15

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:02', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '90d80b59-b3b7-4a71-bf9d-41d8b3f326a6'	System	13 Aug 2020 02:12:15
User entered 'No (N)'	System	13 Aug 2020 02:12:15

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '90d80b59-b3b7-4a71-bf9d-41d8b3f326a6'	System	13 Aug 2020 02:12:15
User entered 'None (1)'	System	13 Aug 2020 02:12:15

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '90d80b59-b3b7-4a71-bf9d-41d8b3f326a6'	System	13 Aug 2020 02:12:15
User entered '12 Aug 2020 21:12'	System	13 Aug 2020 02:12:15

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:04', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'None (0)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:32:11', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'None (0)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:32:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'None (0)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:35:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294' User entered 'None (0)'	System	06 Aug 2020 22:36:13
	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:32:26', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'None (0)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:32:29', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'None (0)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:32:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294'	System	06 Aug 2020 22:36:13
User entered 'No (N)'	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-06T17:36:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5559ab3b-deda-4c71-bae8-01a7d62ab294' User entered '06 Aug 2020 17:36'	System	06 Aug 2020 22:36:13
	System	06 Aug 2020 22:36:13

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 17:25'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 19:55'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:52', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:38:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:39:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:39:02', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:39:04', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'None (0)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:39:07', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered 'No (N)'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-07T11:39:10', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'caa25502-bcfb-41af-a235-af1cff816cb1'	System	07 Aug 2020 16:39:15
User entered '07 Aug 2020 11:39'	System	07 Aug 2020 16:39:15

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '06 Aug 2020 20:50'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 2'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:55', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:24:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:02', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:07', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'None (0)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:12', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered 'No (N)'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T00:25:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'b5e10df3-4132-4ca3-b88e-311f97669e17'	System	08 Aug 2020 05:25:23
User entered '08 Aug 2020 00:25'	System	08 Aug 2020 05:25:23

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 3'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:01', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:03', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:11', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'None (0)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered 'No (N)'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-08T14:04:18', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'aad3c5fe-2c83-4984-9421-b33a276958e4'	System	08 Aug 2020 19:04:22
User entered '08 Aug 2020 14:04'	System	08 Aug 2020 19:04:22

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 4'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:31', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'None (0)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:33', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'None (0)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'None (0)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e' User entered 'None (0)'	System	09 Aug 2020 18:25:52
	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:40', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'None (0)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'None (0)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered 'No (N)'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-09T13:25:47', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0193cba0-a050-4407-9639-6bbe57cde44e'	System	09 Aug 2020 18:25:52
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 18:25:52

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 5'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:34:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:10', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:13', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'None (0)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:23', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'None (0)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:37', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered 'Yes (Y)'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-10T21:35:40', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '16e7df4d-2e28-464b-93b5-153cb8d1661b'	System	11 Aug 2020 02:35:44
User entered '10 Aug 2020 21:35'	System	11 Aug 2020 02:35:44

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 6'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f' User entered 'None (0)'	System	12 Aug 2020 03:23:10
	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f'	System	12 Aug 2020 03:23:10
User entered 'None (0)'	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:48', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f' User entered 'None (0)'	System	12 Aug 2020 03:23:10
	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:51', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f' User entered 'None (0)'	System	12 Aug 2020 03:23:10
	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f' User entered 'None (0)'	System	12 Aug 2020 03:23:10
	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:22:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f' User entered 'None (0)'	System	12 Aug 2020 03:23:10
	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:23:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f'	System	12 Aug 2020 03:23:10
User entered 'No (N)'	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-11T22:23:03', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '3c408b51-de7b-4ce8-8f0d-e5802b35827f'	System	12 Aug 2020 03:23:10
User entered '11 Aug 2020 22:23'	System	12 Aug 2020 03:23:10

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 7'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eecd-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'No interference with activity (1)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:24', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eeed-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'None (0)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:26', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eeed-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'None (0)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:28', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eecd-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'None (0)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eeed-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'None (0)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eccd-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'None (0)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:37', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eeed-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered 'No (N)'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-12T21:12:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5914d868-eeed-4b6d-a0a6-da9fa9aef11e'	System	13 Aug 2020 02:12:43
User entered '12 Aug 2020 21:12'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	13 Aug 2020 02:12:43
User entered 'Day 8'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:25:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4146f2e5-3dfa-4279-944e-46ef5d2576da'	System	14 Aug 2020 03:25:42
User entered 'No interference with activity (1)'	System	14 Aug 2020 03:25:42

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:25:38', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4146f2e5-3dfa-4279-944e-46ef5d2576da'	System	14 Aug 2020 03:25:42
User entered '13 Aug 2020 22:25'	System	14 Aug 2020 03:25:42

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	13 Aug 2020 02:12:43
User entered 'Day 9'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-14T17:16:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '782402c0-a783-4813-9096-2fe1f5359a24'	System	14 Aug 2020 22:16:52
User entered 'None (0)'	System	14 Aug 2020 22:16:52

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-14T17:16:47', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '782402c0-a783-4813-9096-2fe1f5359a24'	System	14 Aug 2020 22:16:52
User entered '14 Aug 2020 17:16'	System	14 Aug 2020 22:16:52

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 02:12:43

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	13 Aug 2020 02:11:59
User entered 'Day 8'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:25:44', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '852d75f7-a7a3-428e-929a-2f939da78a71'	System	14 Aug 2020 03:25:54
User entered 'No (N)'	System	14 Aug 2020 03:25:54

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-13T22:25:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '852d75f7-a7a3-428e-929a-2f939da78a71'	System	14 Aug 2020 03:25:54
User entered '13 Aug 2020 22:25'	System	14 Aug 2020 03:25:54

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	13 Aug 2020 02:11:59
User entered 'Day 9'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-14T17:16:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ba968a79-fd14-47af-accf-5ced46446cd9'	System	14 Aug 2020 22:17:03
User entered 'No (N)'	System	14 Aug 2020 22:17:03

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-08-14T17:16:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ba968a79-fd14-47af-accf-5ced46446cd9'	System	14 Aug 2020 22:17:03
User entered '14 Aug 2020 17:16'	System	14 Aug 2020 22:17:03

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 02:11:59

US3092047

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 02:11:59

US3092047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 20:54:29
User entered 'Yes (Y)'	System	14 Sep 2020 20:54:15
	Vicki Martinez (b) (4)	14 Sep 2020 20:54:15
	(b) (4)	

US3092047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	14 Sep 2020 20:54:29
User entered '13 Aug 2020' reason for change: Data Entry Error	System	14 Sep 2020 20:54:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Vicki Martinez (b) (4)	14 Sep 2020 20:54:15
User entered '1 ' (non-conformant).	(b) (4)	14 Sep 2020 20:54:15

US3092047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Vicki Martinez (b) (4)	14 Sep 2020 20:54:29
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	14 Sep 2020 20:54:15
	(b) (4)	

US3092047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	14 Sep 2020 20:54:15

US3092047

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 11:35:38

US3092047

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	14 Sep 2020 11:35:38

US3092047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	14 Sep 2020 20:54:58

US3092047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '20 Aug 2020'	Vicki Martinez (b) (4)	14 Sep 2020 20:54:58

US3092047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	Vicki Martinez (b) (4)	14 Sep 2020 20:54:58

US3092047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	14 Sep 2020 20:54:58

US3092047

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 11:35:48

US3092047

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	14 Sep 2020 11:35:48

US3092047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4)	14 Sep 2020 20:55:11

US3092047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '27 Aug 2020'	Vicki Martinez (b) (4)	14 Sep 2020 20:55:11

US3092047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	Vicki Martinez (b) (4)	14 Sep 2020 20:55:11

US3092047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Vicki Martinez (b) (4)	14 Sep 2020 20:55:11

US3092047

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 11:35:57

US3092047

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	14 Sep 2020 11:35:57

US3092047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:13:18

US3092047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:19:20
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit out of window.' (Site from System).	Catina Adams (b) (4) (b) (4)	30 Sep 2020 19:35:50
Amendment Manager: User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 23:46:37
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 08:03:37
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Patient had a sick visit on August 10th.' (Site from System).	Vicki Martinez (b) (4) (b) (4)	15 Sep 2020 16:30:39
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 21:13:18
User entered '14 Sep 2020'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:13:18

US3092047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	14 Sep 2020 21:13:18

US3092047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'VISIT2'	System	14 Sep 2020 21:13:18

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Pre-Dose (PREDOSE)'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '14 Sep 2020' reason for change: Data Entry Error	System	14 Sep 2020 21:55:05
User opened query 'Data is required. Please provide.' (Site from System).	Catina Adams (b) (4)	14 Sep 2020 21:55:05
User entered empty.	(b) (4)	
	System	14 Sep 2020 21:52:49
	Catina Adams (b) (4)	14 Sep 2020 21:52:49
	(b) (4)	

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '15:19'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '14 Sep 2020 15:19'	System	14 Sep 2020 21:55:05
User entered empty.	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '36.1' C	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Oral (Oral)'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '87'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'bpm'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '17'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'breaths/min'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '129'	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '71'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Post-Dose (POSTDOSE)'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14 Sep 2020'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '16:21'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '14 Sep 2020 16:21'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '98.1' F	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Oral (Oral)'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '90'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'bpm'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '18'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'breaths/min'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '120'	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '89'	Catina Adams (b) (4)	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	14 Sep 2020 21:52:49

US3092047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:12:48

US3092047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14 Sep 2020'	Catina Adams (b) (4)	14 Sep 2020 21:12:48

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14 Sep 2020'	Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '15:47'	Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '14 Sep 2020 15:47'	System	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Left Arm (LEFT ARM)'	Catina Adams (b) (4)	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'ONCE'	System	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:06:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 21:08:52

US3092047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:59:01

US3092047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14 Sep 2020'	Catina Adams (b) (4)	14 Sep 2020 21:59:01

US3092047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '15:46'	Catina Adams (b) (4)	14 Sep 2020 21:59:01

US3092047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '14 Sep 2020 15:46'	System	14 Sep 2020 21:59:01

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14 Sep 2020'	Catina Adams (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '15:41'	Catina Adams (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '14 Sep 2020 15:41'	System	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 16:28:25
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Dec 2020 16:28:25
User entered '15:41'	Catina Adams (b) (4) (b) (4)	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered empty.	System	31 Dec 2020 16:28:25
User entered '14 Sep 2020 15:41'	System	14 Sep 2020 21:59:54

US3092047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	14 Sep 2020 21:59:22

US3092047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'I'	System	14 Sep 2020 21:59:22

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4599b116-d598-44bd-baac-cba1cf396618'	System	14 Sep 2020 21:17:57
User entered 'Yes (Y)'	System	14 Sep 2020 21:17:57

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4599b116-d598-44bd-baac-cba1cf396618'	System	14 Sep 2020 21:17:57
User entered '98.1'	System	14 Sep 2020 21:17:57

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4599b116-d598-44bd-baac-cba1cf396618'	System	14 Sep 2020 21:17:57
User entered 'No (N)'	System	14 Sep 2020 21:17:57

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '4599b116-d598-44bd-baac-cba1cf396618'	System	14 Sep 2020 21:17:57
User entered '14 Sep 2020 16:17'	System	14 Sep 2020 21:17:57

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 16:07'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 18:37'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:20', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dcc84c69-8f54-440c-b540-7a5a059e96b6'	System	15 Sep 2020 03:23:46
User entered 'Yes (Y)'	System	15 Sep 2020 03:23:46

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:31', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dcc84c69-8f54-440c-b540-7a5a059e96b6'	System	15 Sep 2020 03:23:46
User entered '98.1'	System	15 Sep 2020 03:23:46

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dcc84c69-8f54-440c-b540-7a5a059e96b6'	System	15 Sep 2020 03:23:46
User entered 'No (N)'	System	15 Sep 2020 03:23:46

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:38', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dcc84c69-8f54-440c-b540-7a5a059e96b6'	System	15 Sep 2020 03:23:46
User entered '14 Sep 2020 22:23'	System	15 Sep 2020 03:23:46

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 19:32'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 2'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 3'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:57', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6332d44c-0e0d-4f90-9493-40ee144ebc98'	System	16 Sep 2020 19:18:24
User entered 'Yes (Y)'	System	16 Sep 2020 19:18:24

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:18:14', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6332d44c-0e0d-4f90-9493-40ee144ebc98'	System	16 Sep 2020 19:18:24
User entered '97.9'	System	16 Sep 2020 19:18:24

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:18:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6332d44c-0e0d-4f90-9493-40ee144ebc98'	System	16 Sep 2020 19:18:24
User entered 'No (N)'	System	16 Sep 2020 19:18:24

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:18:19', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6332d44c-0e0d-4f90-9493-40ee144ebc98'	System	16 Sep 2020 19:18:24
User entered '16 Sep 2020 14:18'	System	16 Sep 2020 19:18:24

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 4'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ffb31d1f-1254-48bc-823f-389572e6dbf5'	System	17 Sep 2020 21:13:39
User entered 'Yes (Y)'	System	17 Sep 2020 21:13:39

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:28', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ffb31d1f-1254-48bc-823f-389572e6dbf5'	System	17 Sep 2020 21:13:39
User entered '98.2'	System	17 Sep 2020 21:13:39

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ffb31d1f-1254-48bc-823f-389572e6dbf5'	System	17 Sep 2020 21:13:39
User entered 'No (N)'	System	17 Sep 2020 21:13:39

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ffb31d1f-1254-48bc-823f-389572e6dbf5'	System	17 Sep 2020 21:13:39
User entered '17 Sep 2020 16:13'	System	17 Sep 2020 21:13:39

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 5'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 6'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f09ddc59-61b2-447d-9b66-438a030aeb47'	System	19 Sep 2020 19:08:48
User entered 'Yes (Y)'	System	19 Sep 2020 19:08:48

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f09ddc59-61b2-447d-9b66-438a030aeb47'	System	19 Sep 2020 19:08:48
User entered '98.2'	System	19 Sep 2020 19:08:48

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f09ddc59-61b2-447d-9b66-438a030aeb47'	System	19 Sep 2020 19:08:48
User entered 'No (N)'	System	19 Sep 2020 19:08:48

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f09ddc59-61b2-447d-9b66-438a030aeb47'	System	19 Sep 2020 19:08:48
User entered '19 Sep 2020 14:08'	System	19 Sep 2020 19:08:48

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 7'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '999dca0f-9c51-4ab8-b0eb-14d39a469d81'	System	21 Sep 2020 05:18:38
User entered 'Yes (Y)'	System	21 Sep 2020 05:18:38

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:31', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '999dca0f-9c51-4ab8-b0eb-14d39a469d81'	System	21 Sep 2020 05:18:38
User entered '98.1'	System	21 Sep 2020 05:18:38

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '999dca0f-9c51-4ab8-b0eb-14d39a469d81'	System	21 Sep 2020 05:18:38
User entered 'No (N)'	System	21 Sep 2020 05:18:38

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '999dca0f-9c51-4ab8-b0eb-14d39a469d81'	System	21 Sep 2020 05:18:38
User entered '21 Sep 2020 00:18'	System	21 Sep 2020 05:18:38

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '987a1e0c-d3bf-4a37-b937-15d08e82ef2a'	System	14 Sep 2020 21:17:33
User entered 'None (1)'	System	14 Sep 2020 21:17:33

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:12', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '987a1e0c-d3bf-4a37-b937-15d08e82ef2a'	System	14 Sep 2020 21:17:33
User entered 'No (N)'	System	14 Sep 2020 21:17:33

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:17', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '987a1e0c-d3bf-4a37-b937-15d08e82ef2a'	System	14 Sep 2020 21:17:33
User entered 'No (N)'	System	14 Sep 2020 21:17:33

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:22', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '987a1e0c-d3bf-4a37-b937-15d08e82ef2a'	System	14 Sep 2020 21:17:33
User entered 'None (1)'	System	14 Sep 2020 21:17:33

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:17:25', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '987a1e0c-d3bf-4a37-b937-15d08e82ef2a'	System	14 Sep 2020 21:17:33
User entered '14 Sep 2020 16:17'	System	14 Sep 2020 21:17:33

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 16:07'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 18:37'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7e78ab0a-cdb3-4854-9140-0e4e39b857c9'	System	15 Sep 2020 03:23:24
User entered 'None (1)'	System	15 Sep 2020 03:23:24

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:07', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7e78ab0a-cdb3-4854-9140-0e4e39b857c9'	System	15 Sep 2020 03:23:24
User entered 'No (N)'	System	15 Sep 2020 03:23:24

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:09', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7e78ab0a-cdb3-4854-9140-0e4e39b857c9'	System	15 Sep 2020 03:23:24
User entered 'No (N)'	System	15 Sep 2020 03:23:24

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:11', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7e78ab0a-cdb3-4854-9140-0e4e39b857c9'	System	15 Sep 2020 03:23:24
User entered 'None (1)'	System	15 Sep 2020 03:23:24

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:14', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7e78ab0a-cdb3-4854-9140-0e4e39b857c9'	System	15 Sep 2020 03:23:24
User entered '14 Sep 2020 22:23'	System	15 Sep 2020 03:23:24

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 19:32'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 2'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 3'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f82e77a8-fd5a-47f2-a2e6-de7ed86350fa'	System	16 Sep 2020 19:17:55
User entered 'None (1)'	System	16 Sep 2020 19:17:55

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:44', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f82e77a8-fd5a-47f2-a2e6-de7ed86350fa'	System	16 Sep 2020 19:17:55
User entered 'No (N)'	System	16 Sep 2020 19:17:55

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f82e77a8-fd5a-47f2-a2e6-de7ed86350fa'	System	16 Sep 2020 19:17:55
User entered 'No (N)'	System	16 Sep 2020 19:17:55

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:47', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f82e77a8-fd5a-47f2-a2e6-de7ed86350fa'	System	16 Sep 2020 19:17:55
User entered 'None (1)'	System	16 Sep 2020 19:17:55

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:50', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f82e77a8-fd5a-47f2-a2e6-de7ed86350fa'	System	16 Sep 2020 19:17:55
User entered '16 Sep 2020 14:17'	System	16 Sep 2020 19:17:55

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 4'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:55', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7ae2b6ac-b338-43eb-b1b5-8d001506dc79'	System	17 Sep 2020 21:13:09
User entered 'None (1)'	System	17 Sep 2020 21:13:09

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7ae2b6ac-b338-43eb-b1b5-8d001506dc79'	System	17 Sep 2020 21:13:09
User entered 'No (N)'	System	17 Sep 2020 21:13:09

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7ae2b6ac-b338-43eb-b1b5-8d001506dc79'	System	17 Sep 2020 21:13:09
User entered 'No (N)'	System	17 Sep 2020 21:13:09

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:02', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7ae2b6ac-b338-43eb-b1b5-8d001506dc79'	System	17 Sep 2020 21:13:09
User entered 'None (1)'	System	17 Sep 2020 21:13:09

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:13:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7ae2b6ac-b338-43eb-b1b5-8d001506dc79'	System	17 Sep 2020 21:13:09
User entered '17 Sep 2020 16:13'	System	17 Sep 2020 21:13:09

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 5'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 6'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6ea495c5-b91a-4c12-a8db-5d4a5d0bc775'	System	19 Sep 2020 19:08:34
User entered 'None (1)'	System	19 Sep 2020 19:08:34

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:23', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6ea495c5-b91a-4c12-a8db-5d4a5d0bc775'	System	19 Sep 2020 19:08:34
User entered 'No (N)'	System	19 Sep 2020 19:08:34

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:24', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6ea495c5-b91a-4c12-a8db-5d4a5d0bc775'	System	19 Sep 2020 19:08:34
User entered 'No (N)'	System	19 Sep 2020 19:08:34

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:26', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6ea495c5-b91a-4c12-a8db-5d4a5d0bc775'	System	19 Sep 2020 19:08:34
User entered 'None (1)'	System	19 Sep 2020 19:08:34

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:29', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6ea495c5-b91a-4c12-a8db-5d4a5d0bc775'	System	19 Sep 2020 19:08:34
User entered '19 Sep 2020 14:08'	System	19 Sep 2020 19:08:34

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 7'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:03', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6b2d0830-e6c8-463f-8c1f-ec6751260945'	System	21 Sep 2020 05:18:31
User entered 'None (1)'	System	21 Sep 2020 05:18:31

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6b2d0830-e6c8-463f-8c1f-ec6751260945'	System	21 Sep 2020 05:18:31
User entered 'No (N)'	System	21 Sep 2020 05:18:31

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6b2d0830-e6c8-463f-8c1f-ec6751260945'	System	21 Sep 2020 05:18:31
User entered 'No (N)'	System	21 Sep 2020 05:18:31

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6b2d0830-e6c8-463f-8c1f-ec6751260945'	System	21 Sep 2020 05:18:31
User entered 'None (1)'	System	21 Sep 2020 05:18:31

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:18:14', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '6b2d0830-e6c8-463f-8c1f-ec6751260945'	System	21 Sep 2020 05:18:31
User entered '21 Sep 2020 00:18'	System	21 Sep 2020 05:18:31

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:44', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'None (0)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered 'No (N)'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T16:16:53', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8881f902-993f-4667-9fc4-6d3e9d956e53'	System	14 Sep 2020 21:17:01
User entered '14 Sep 2020 16:16'	System	14 Sep 2020 21:17:01

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 16:07'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 18:37'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:50', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:52', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:53', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:55', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:57', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered 'None (0)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:22:58', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dad8'	System	15 Sep 2020 03:23:09
User entered 'No (N)'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-14T22:23:01', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '167aa11e-4964-4bfa-a74c-ff43da7dadbb8'	System	15 Sep 2020 03:23:09
User entered '14 Sep 2020 22:23'	System	15 Sep 2020 03:23:09

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '14 Sep 2020 19:32'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 2'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 3'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:25', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:27', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:28', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:31', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:33', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'None (0)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered 'No (N)'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-16T14:17:38', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '736a8832-b65a-4573-b74d-d2195e0f8fac'	System	16 Sep 2020 19:17:44
User entered '16 Sep 2020 14:17'	System	16 Sep 2020 19:17:44

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 4'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:40', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:43', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'None (0)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:50', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered 'No (N)'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-17T16:12:52', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'f229ec86-621d-446d-ac46-bf26758d7233'	System	17 Sep 2020 21:12:58
User entered '17 Sep 2020 16:12'	System	17 Sep 2020 21:12:58

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 5'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 6'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:01', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:03', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:10', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:12', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'None (0)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered 'No (N)'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-19T14:08:18', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'dc952276-cae9-48f2-b01e-ff2f1abaa699'	System	19 Sep 2020 19:08:21
User entered '19 Sep 2020 14:08'	System	19 Sep 2020 19:08:21

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	14 Sep 2020 21:08:52
User entered 'Day 7'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:47', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:50', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:51', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'None (0)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:57', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0'	System	21 Sep 2020 05:18:04
User entered 'No (N)'	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-09-21T00:17:59', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5519bba1-ab3d-4d30-af00-3bcd761a26c0' User entered '21 Sep 2020 00:17'	System	21 Sep 2020 05:18:04
	System	21 Sep 2020 05:18:04

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:08:52

US3092047

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:06:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:08:52

US3092047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:05:50

US3092047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:05:50

US3092047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:05:50

US3092047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:05:50

US3092047

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	30 Sep 2020 14:30:41

US3092047

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	30 Sep 2020 14:30:41

US3092047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	30 Sep 2020 14:30:59

US3092047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '29 Sep 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	30 Sep 2020 14:30:59

US3092047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4)	30 Sep 2020 14:30:59

US3092047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	30 Sep 2020 14:30:59

US3092047

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	30 Sep 2020 14:31:06

US3092047

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	30 Sep 2020 14:31:06

US3092047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 22:46:10

US3092047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '6 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 22:46:10

US3092047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 22:46:10

US3092047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	06 Oct 2020 22:46:10

US3092047

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	06 Oct 2020 22:46:14

US3092047

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	06 Oct 2020 22:46:14

US3092047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:07:43

US3092047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:49:04
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CONFIRM AND CORRECT' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 22:07:59
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Nov 2020 22:07:43
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:07:43

US3092047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:07:43

US3092047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'VISIT3'	System	11 Nov 2020 22:07:43

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14:10'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '11 Nov 2020 14:10'	System	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '90'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'bpm'	System	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'breaths/min'	System	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '129'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '67'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'mmHg'	System	11 Nov 2020 22:08:59

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 21:47:48

US3092047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 21:47:48

US3092047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:30

US3092047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:30

US3092047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:49

US3092047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:49

US3092047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '14:24'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 22:09:49

US3092047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:06:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered '11 Nov 2020 14:24'	System	11 Nov 2020 22:09:49

US3092047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:09:58

US3092047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:48
User entered 'I'	System	10 Nov 2020 01:09:58

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 64'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-10-06T03:29:23', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5472f0de-e35b-46e7-a91d-47b35390e11b'	System	06 Oct 2020 08:29:40
User entered 'No (N)'	System	06 Oct 2020 08:29:40

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-10-06T03:29:32', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5472f0de-e35b-46e7-a91d-47b35390e11b'	System	06 Oct 2020 08:29:40
User entered 'No (N)'	System	06 Oct 2020 08:29:40

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-10-06T03:29:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '5472f0de-e35b-46e7-a91d-47b35390e11b' User entered '06 Oct 2020 03:29:35'	System	06 Oct 2020 08:29:40
	System	06 Oct 2020 08:29:40

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:17:43
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 71'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092047

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 78'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:06:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092047

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 92'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
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US3092047

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:06:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:06:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Generated On: 09 Jun 2021 15:06:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 99'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered 'Day 106'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3092047

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:06:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:06:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 22:16:24

US3092047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:23:22
Data entry locked.	System	06 Aug 2020 22:16:24
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 22:16:24

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-05T00:26:35', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7b0fcbe5-5746-4395-ab39-8a366086ebfc'	System	05 Dec 2020 06:26:49
User entered 'No (N)'	System	05 Dec 2020 06:26:49

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-05T00:26:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7b0fcbe5-5746-4395-ab39-8a366086ebfc'	System	05 Dec 2020 06:26:49
User entered 'No (N)'	System	05 Dec 2020 06:26:49

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-05T00:26:44', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '7b0fcbe5746-4395-ab39-8a366086ebfc'	System	05 Dec 2020 06:26:49
User entered '05 Dec 2020 00:26:44'	System	05 Dec 2020 06:26:49

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-13T01:13:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ce99dec-e722-42b7-a4b9-dcca8817180a'	System	13 Dec 2020 07:13:44
User entered 'No (N)'	System	13 Dec 2020 07:13:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-13T01:13:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ce99dec-e722-42b7-a4b9-dcca8817180a'	System	13 Dec 2020 07:13:44
User entered 'No (N)'	System	13 Dec 2020 07:13:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-13T01:13:37', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ce99dec-e722-42b7-a4b9-dcca8817180a' User entered '13 Dec 2020 01:13:37'	System	13 Dec 2020 07:13:44
	System	13 Dec 2020 07:13:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-19T13:20:54', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '233a2145-13c0-42c1-b08b-7501c3a0f310'	System	19 Dec 2020 19:21:21
User entered 'No (N)'	System	19 Dec 2020 19:21:21

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-19T13:21:05', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '233a2145-13c0-42c1-b08b-7501c3a0f310'	System	19 Dec 2020 19:21:21
User entered 'No (N)'	System	19 Dec 2020 19:21:21

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-19T13:21:15', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '233a2145-13c0-42c1-b08b-7501c3a0f310'	System	19 Dec 2020 19:21:21
User entered '19 Dec 2020 13:21:15'	System	19 Dec 2020 19:21:21

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-26T00:25:40', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '606eeec-e140-4869-870e-3a3487880ecb'	System	26 Dec 2020 06:25:53
User entered 'No (N)'	System	26 Dec 2020 06:25:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-26T00:25:21', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '606eeec-e140-4869-870e-3a3487880ecb'	System	26 Dec 2020 06:25:53
User entered 'No (N)'	System	26 Dec 2020 06:25:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2020-12-26T00:25:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '606eeec-e140-4869-870e-3a3487880ecb'	System	26 Dec 2020 06:25:53
User entered '26 Dec 2020 00:25:46'	System	26 Dec 2020 06:25:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-10T21:08:25', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '25d8b4ee-0a93-4977-b5e1-f3d54331f5f0'	System	11 Jan 2021 03:08:37
User entered 'No (N)'	System	11 Jan 2021 03:08:37

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-10T21:08:27', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '25d8b4ee-0a93-4977-b5e1-f3d54331f5f0'	System	11 Jan 2021 03:08:37
User entered 'No (N)'	System	11 Jan 2021 03:08:37

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-10T21:08:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '25d8b4ee-0a93-4977-b5e1-f3d54331f5f0'	System	11 Jan 2021 03:08:37
User entered '10 Jan 2021 21:08:30'	System	11 Jan 2021 03:08:37

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-16T23:56:34', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c227fe26-b647-47f0-ac9c-3dd3fb9b0bbc'	System	17 Jan 2021 05:56:46
User entered 'No (N)'	System	17 Jan 2021 05:56:46

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-16T23:56:39', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c227fe26-b647-47f0-ac9c-3dd3fb9b0bbc'	System	17 Jan 2021 05:56:46
User entered 'No (N)'	System	17 Jan 2021 05:56:46

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-16T23:56:42', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c227fe26-b647-47f0-ac9c-3dd3fb9b0bbc'	System	17 Jan 2021 05:56:46
User entered '16 Jan 2021 23:56:42'	System	17 Jan 2021 05:56:46

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-24T21:46:18', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '2d152823-3de4-420b-b11d-1471740b70e6'	System	25 Jan 2021 03:46:25
User entered 'No (N)'	System	25 Jan 2021 03:46:25

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-24T21:46:20', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '2d152823-3de4-420b-b11d-1471740b70e6'	System	25 Jan 2021 03:46:25
User entered 'No (N)'	System	25 Jan 2021 03:46:25

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0049715e269547)', Time: '2021-01-24T21:46:23', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '2d152823-3de4-420b-b11d-1471740b70e6'	System	25 Jan 2021 03:46:25
User entered '24 Jan 2021 21:46:23'	System	25 Jan 2021 03:46:25

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-10T19:28:59', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '87383914-761e-4da7-baac-d087e62e7e92'	System	11 Feb 2021 01:29:11
User entered 'No (N)'	System	11 Feb 2021 01:29:11

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-10T19:29:03', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '87383914-761e-4da7-baac-d087e62e7e92'	System	11 Feb 2021 01:29:11
User entered 'No (N)'	System	11 Feb 2021 01:29:11

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-10T19:29:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '87383914-761e-4da7-baac-d087e62e7e92'	System	11 Feb 2021 01:29:11
User entered '10 Feb 2021 19:29:06'	System	11 Feb 2021 01:29:11

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-14T01:43:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8aa7c263-705c-462b-82da-58ca86a68562'	System	14 Feb 2021 07:43:51
User entered 'No (N)'	System	14 Feb 2021 07:43:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-14T01:43:46', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8aa7c263-705c-462b-82da-58ca86a68562'	System	14 Feb 2021 07:43:51
User entered 'No (N)'	System	14 Feb 2021 07:43:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-14T01:43:49', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8aa7c263-705c-462b-82da-58ca86a68562'	System	14 Feb 2021 07:43:51
User entered '14 Feb 2021 01:43:49'	System	14 Feb 2021 07:43:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-20T09:29:36', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'd40068db-54bd-4dbc-b452-2e71741b4ac5'	System	20 Feb 2021 15:29:44
User entered 'No (N)'	System	20 Feb 2021 15:29:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-20T09:29:38', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'd40068db-54bd-4dbc-b452-2e71741b4ac5'	System	20 Feb 2021 15:29:44
User entered 'No (N)'	System	20 Feb 2021 15:29:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-20T09:29:41', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'd40068db-54bd-4dbc-b452-2e71741b4ac5'	System	20 Feb 2021 15:29:44
User entered '20 Feb 2021 09:29:41'	System	20 Feb 2021 15:29:44

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-28T23:11:43', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8f91dbab-1021-4f69-9b26-d28c51cf1c5f'	System	01 Mar 2021 05:11:53
User entered 'No (N)'	System	01 Mar 2021 05:11:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-28T23:11:45', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8f91dbab-1021-4f69-9b26-d28c51cf1c5f'	System	01 Mar 2021 05:11:53
User entered 'No (N)'	System	01 Mar 2021 05:11:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-28T23:11:48', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '8f91dbab-1021-4f69-9b26-d28c51cf1c5f'	System	01 Mar 2021 05:11:53
User entered '28 Feb 2021 23:11:48'	System	01 Mar 2021 05:11:53

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-17T10:25:24', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ff76385-9afc-4a81-b597-1a7d11e2d813'	System	17 Mar 2021 15:25:36
User entered 'No (N)'	System	17 Mar 2021 15:25:36

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-17T10:25:28', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ff76385-9afc-4a81-b597-1a7d11e2d813'	System	17 Mar 2021 15:25:36
User entered 'No (N)'	System	17 Mar 2021 15:25:36

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-17T10:25:30', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '0ff76385-9afc-4a81-b597-1a7d11e2d813'	System	17 Mar 2021 15:25:36
User entered '17 Mar 2021 10:25:30'	System	17 Mar 2021 15:25:36

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-21T01:36:04', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c28a8c25-a1fc-4065-b4d2-f6b789c3b373'	System	21 Mar 2021 06:36:13
User entered 'No (N)'	System	21 Mar 2021 06:36:13

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-21T01:36:06', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c28a8c25-a1fc-4065-b4d2-f6b789c3b373'	System	21 Mar 2021 06:36:13
User entered 'No (N)'	System	21 Mar 2021 06:36:13

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-21T01:36:08', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'c28a8c25-a1fc-4065-b4d2-f6b789c3b373'	System	21 Mar 2021 06:36:13
User entered '21 Mar 2021 01:36:08'	System	21 Mar 2021 06:36:13

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-27T01:04:36-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ad88f5ae-a7b6-40b6-afee-bafa2360dbbb'	System	27 Mar 2021 06:05:26
User entered 'Yes (Y)'	System	27 Mar 2021 06:05:26

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-27T01:04:40-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ad88f5ae-a7b6-40b6-afee-bafa2360dbbb'	System	27 Mar 2021 06:05:26
User entered 'No (N)'	System	27 Mar 2021 06:05:26

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-27T01:04:46-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ad88f5ae-a7b6-40b6-afee-bafa2360dbbb'	System	27 Mar 2021 06:05:26
User entered 'No (N)'	System	27 Mar 2021 06:05:26

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-27T01:05:20-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ad88f5ae-a7b6-40b6-afee-bafa2360dbbb'	System	27 Mar 2021 06:05:26
User entered 'No (N)'	System	27 Mar 2021 06:05:26

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-03-27T01:05:24-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: 'ad88f5ae-a7b6-40b6-afee-bafa2360dbbb' User entered '27 Mar 2021 01:05:24'	System	27 Mar 2021 06:05:26
	System	27 Mar 2021 06:05:26

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-04-03T00:15:41-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '98cd1d79-b4a9-4145-9ba1-ccfcb7013582' User entered 'No (N)'	System	03 Apr 2021 05:15:51
	System	03 Apr 2021 05:15:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-04-03T00:15:43-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '98cd1d79-b4a9-4145-9ba1-ccfcb7013582'	System	03 Apr 2021 05:15:51
User entered 'No (N)'	System	03 Apr 2021 05:15:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-04-03T00:15:46-05:00', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '98cd1d79-b4a9-4145-9ba1-ccfcb7013582'	System	03 Apr 2021 05:15:51
User entered '03 Apr 2021 00:15:46'	System	03 Apr 2021 05:15:51

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:23:22

US3092047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:06:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:23:22
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:23:22

US3092047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:06:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-28T23:11:56', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '88829894-4b3d-43fb-b90b-8c8c4eca46e2'	System	01 Mar 2021 05:12:01
User entered 'No (N)'	System	01 Mar 2021 05:12:01

US3092047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:06:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:40:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10edd2b89286371f)', Time: '2021-02-28T23:11:59', User OID: 'PatientReportedOutcome (US3092047)', ODM File OID: '88829894-4b3d-43fb-b90b-8c8c4eca46e2'	System	01 Mar 2021 05:12:01
User entered '28 Feb 2021 23:11:59'	System	01 Mar 2021 05:12:01

US3092047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:10:08

US3092047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 10AUG2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:39:31
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 10AUG2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'information has been entered ' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:31:42
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 10AUG2020 is reported under Illness Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:01:42
User entered '09 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 01:10:08

US3092047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:10:08

US3092047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:10:08

US3092047

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:10:12

US3092047

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 21:47:37
User entered 'I'	System	10 Nov 2020 01:10:12

US3092047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:08

US3092047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 10AUG2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:40:53
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 10AUG2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' answered with 'information has been entered' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:31:30
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection date is recorded as 10AUG2020 under Illness Visit Day 1 in PPD central lab. however same is missing in in EDC. Please update the details under appropriate visit Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:44:54
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 16:28:08

US3092047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:08

US3092047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:08

US3092047

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:28:35

US3092047

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User entered 'I'	System	10 Dec 2020 16:28:35

US3092047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:56:50

US3092047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:56:50

US3092047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:56:50

US3092047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:56:50

US3092047

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:43

US3092047

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User entered 'I'	System	12 Jan 2021 17:03:43

US3092047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:14

US3092047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:14

US3092047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:14

US3092047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '1st attempt made on 02/08/21 2nd attempt made on 02/09/21 3rd attempt made on 02/10/21'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:14

US3092047

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:39:31

US3092047

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:59
User entered 'I'	System	12 Feb 2021 17:39:31

US3092047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:09

US3092047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 17:02:09

US3092047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:03:29

US3092047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered '12 Apr 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:03:45
User entered '09 Apr 2021'		14 Apr 2021 17:03:29

US3092047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:03:29

US3092047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:06:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:03:29

US3092047

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:03:34

US3092047

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:06:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 17:03:34

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 20:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Dec 2020 20:01:21
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Dec 2020 20:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 18:10:43
User entered empty; reason for change Data Entry Error	Catina Adams (b) (4)	17 Oct 2020 18:10:43
User entered '04 Sep 2020'	Catina Adams (b) (4)	17 Oct 2020 17:32:18

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Dec 2020 20:01:37
User entered '00:00' reason for change: Data Entry Error	System	19 Dec 2020 20:01:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Dec 2020 20:01:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 20:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Dec 2020 20:01:21
User entered 'un:un' (non-conformant).	System	19 Dec 2020 20:01:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Oct 2020 18:10:43
User entered empty; reason for change Data Entry Error	System	17 Oct 2020 18:10:43
User entered '12:00'	Catina Adams (b) (4)	17 Oct 2020 18:10:43
	(b) (4)	
	Catina Adams (b) (4)	17 Oct 2020 17:32:18
	(b) (4)	

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User entered '10 Aug 2020 00:00'	System	19 Dec 2020 20:01:37
User entered '10 Aug 2020 UN:UN' (non-conformant).	System	19 Dec 2020 20:01:21
User entered empty.	System	17 Oct 2020 18:10:43
User entered '04 Sep 2020 12:00'	System	17 Oct 2020 17:32:18

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Catina Adams (b) (4)	17 Oct 2020 18:10:43
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Catina Adams (b) (4)	17 Oct 2020 17:32:18

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:06:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Dec 2020 20:01:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Dec 2020 20:01:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Dec 2020 20:01:21
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 18:10:43
User entered empty; reason for change Data Entry Error	Catina Adams (b) (4)	17 Oct 2020 18:10:43
User entered 'Yes (Y)'	Catina Adams (b) (4)	17 Oct 2020 17:32:18

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'Day 1 (Day 1)'	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered '10 Aug 2020' reason for change: Data Entry Error	Catina Adams (b) (4)	17 Oct 2020 18:15:51
User entered '3 Sep 2020'	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered '0' reason for change: Data Entry Error	(b) (4) Catina Adams (b) (4)	17 Oct 2020 18:15:51
User entered '1'	(b) (4) Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User closed query 'Per CDM: it appears data is missing. Please provide or consider recording Not Done for applicable fields or if assessment was not done then check that field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 05:29:38
Query 'Per CDM: it appears data is missing. Please provide or consider recording Not Done for applicable fields or if assessment was not done then check that field.' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	25 Nov 2020 12:36:05
User entered '99' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	25 Nov 2020 12:35:47
User opened query 'Per CDM: it appears data is missing. Please provide or consider recording Not Done for applicable fields or if assessment was not done then check that field.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 23:01:52
User entered empty.	Catina Adams (b) (4) (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User entered '%'	System	25 Nov 2020 12:35:47
User entered empty.	System	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44
	(b) (4)	

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'Mild (Mild)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:06:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'None (None)' reason for change: Data Entry Error	Catina Adams (b) (4)	25 Nov 2020 12:35:47
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:32:44

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 04SEP2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 08:48:15
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 04SEP2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'PER SOURCE CORRECTION MADE TO DATE.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 22:00:30
User entered '10 Aug 2020' reason for change: Data Entry Error		10 Mar 2021 22:00:17
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 04SEP2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).		05 Feb 2021 09:49:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-Aug-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).		05 Feb 2021 09:46:56
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-Aug-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'data has been entered ' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:30:22

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Date of Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10-Aug-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM). User entered '4 Sep 2020'	(b) (4), (b) (6) (b) (4) Catina Adams (b) (4) (b) (4)	30 Oct 2020 06:52:49 17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered 'Yes (Y)'	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered 'No (N)'	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:00:17
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		10 Feb 2021 09:39:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'lab unable to provide tracking number please advise' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:41:11
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:19:59
User entered '4 Sep 2020'	Catina Adams (b) (4) (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered 'No (N)'	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
User entered empty.	Catina Adams (b) (4)	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:06:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User entered '0'	System	17 Oct 2020 17:41:06

US3092047

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:06:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 20:03:00

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:06:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:06:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:48
	(b) (4)	

US3092047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:25:48

US3092047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '10 Aug 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Clinic (Clinic)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered 'SICKD1'	System	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '10 Aug 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:43:38
Query 'Data is required. Please provide.' answered with 'no time recorded ' (Site from System).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:02
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Feb 2021 20:23:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Feb 2021 20:23:55
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Feb 2021 20:23:47
User entered 'un:un' (non-conformant).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered empty.	System	02 Feb 2021 20:23:55
User entered '10 Aug 2020 UN:UN' (non-conformant).	System	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:23:47
DataPoint set to visible.	(b) (4) System	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:23:47
DataPoint set to visible.	(b) (4) System	02 Feb 2021 20:22:28

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Other (Other)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '91'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered 'bpm'	System	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '20'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered 'breaths/min'	System	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered 'mmHg'	System	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered missing code ND - Not Done.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User entered 'mmHg'	System	02 Feb 2021 20:23:47

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36

US3092047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36

US3092047

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:19

US3092047

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '10 Aug 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:19

US3092047

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:06:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:33

US3092047

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:04:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '10 Aug 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:33

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:24:45
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:24:45
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:24:45
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	02 Feb 2021 20:24:45

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:06:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 20:24:50

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:00
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:00
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:06:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	02 Feb 2021 20:25:04
	(b) (4)	

US3092047

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:06:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	02 Feb 2021 20:25:04
	(b) (4)	

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:23:21
User entered 'No (N)' reason for change: Data Entry Error		16 Mar 2021 21:23:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:43:04
Query 'Data is required. Please complete.' answered with 'visit has not occurred yet .' (Site from System).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:31:02
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 20:22:11
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:22:11
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:21:59

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	02 Feb 2021 20:22:11
	(b) (4)	
User entered '10 Aug 2020'	destiny robinson (b) (4)	02 Feb 2021 20:21:59
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
	(b) (4)	
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	02 Feb 2021 20:22:11
	(b) (4)	
User entered 'Clinic (Clinic)'	destiny robinson (b) (4)	02 Feb 2021 20:21:59
	(b) (4)	

US3092047

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:06:27

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	16 Mar 2021 21:23:21
User entered empty.	System	02 Feb 2021 20:22:11
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 20:21:59

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:06:27

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:24

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:06:27

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:24

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:06:27

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:24

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:06:27

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:24

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:06:27

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:24

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:27
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:38

US3092047

Folder: Unscheduled 12 Oct 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:06:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:50:27
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:29:03
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 19:54:38

US3092047

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:06:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:57
User closed query 'Per CDM: Per the eDiary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.		28 Apr 2021 08:03:00
' (Site from DM). Query 'Per CDM: Per the eDiary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:55:21
' answered with 'CONFIRMED AND UPDATED SOURCE AND EDC' (Site from DM). User opened query 'Per CDM: Per the eDiary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Headache to the AE page or else clarify.	(b) (4), (b) (6)	19 Apr 2021 06:38:25
' (Site from DM). Query 'Per CDM: Per the eDiary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Underarm Gland Swelling or Tenderness to the AE page or else clarify.	(b) (4), (b) (6)	19 Apr 2021 06:37:21
' canceled (Site from DM). User opened query 'Per CDM: Per the eDiary from Diary Dose 1, the symptom of Headache was still present on Day 8 after dosing. Please review and if correct, please agree to add a solicited AE for the symptom of Underarm Gland Swelling or Tenderness to the AE page or else clarify.	(b) (4), (b) (6)	19 Apr 2021 06:36:52
' (Site from DM). User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:28:51

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:06:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	11 Aug 2020 14:09:18

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:20
DataPoint Verified.		29 Apr 2021 15:32:17
DataPoint Un-verified.		22 Mar 2021 21:53:09
DataPoint Verified.		22 Mar 2021 21:52:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\23.0.	Coder Import (b) (b) (4)	10 Mar 2021 20:28:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (b) (4)	10 Mar 2021 20:28:02
Data point term sent to Coder	System	10 Mar 2021 20:13:21
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' canceled (Site from System).	Coder Import (b) (b) (4)	10 Mar 2021 20:12:56
Data point term sent to Coder	System	10 Mar 2021 20:12:18
Coding entries removed.	Vicki Martinez (b) (b) (4)	10 Mar 2021 20:12:03
User entered 'MUSCULOSKELETAL CHEST PAIN' reason for change: Data Entry Error	Vicki Martinez (b) (b) (4)	10 Mar 2021 20:12:03
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' (Site from System).	Coder Import (b) (b) (4)	07 Mar 2021 16:06:15
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (b) (4)	05 Mar 2021 19:19:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b)	05 Mar 2021 19:19:20
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 19:18:26
User entered 'CHEST PAIN'	(b) (4), (b) (6)	05 Mar 2021 19:18:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:22
DataPoint Verified.		29 Apr 2021 15:32:19
DataPoint Un-verified.		22 Mar 2021 21:53:12
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:54:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:18:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:18:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:23
DataPoint Verified.		29 Apr 2021 15:32:21
DataPoint Un-verified.		22 Mar 2021 21:53:14
DataPoint Verified.		22 Mar 2021 21:53:05
DataPoint Un-verified.		22 Mar 2021 21:52:58
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:54:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:18:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:25
DataPoint Verified.		29 Apr 2021 15:32:23
DataPoint Un-verified.		22 Mar 2021 21:53:16
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:54:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:18:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:27
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '10 Aug 2020'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:28
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:29
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:31
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '13 Aug 2020'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:33
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:34
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Grade 1/Mild (Grade 1/Mild)'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:02:36
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Not Related (NOT RELATED)'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:54:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:18:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:54:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:54:28
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:54:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:18:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'I'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 19:18:02

US3092047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 23:54:28

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:06
DataPoint Verified.		22 Mar 2021 21:52:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (b) (4)	05 Mar 2021 19:21:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (b) (4)	05 Mar 2021 19:21:08
Data point term sent to Coder	System	05 Mar 2021 19:20:28
User entered 'COUGH'	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:08
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:10
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:55:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:11
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:55:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:13
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '10 Aug 2020'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:14
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:16
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:17
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '13 Aug 2020'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:19
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:20
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Grade 1/Mild (Grade 1/Mild)'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:21
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Not Related (NOT RELATED)'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:55:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 23:55:33
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'I'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 19:20:20

US3092047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 23:55:33

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:28
DataPoint Verified.		22 Mar 2021 21:52:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (b) (4)	05 Mar 2021 23:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (b) (4)	05 Mar 2021 23:59:00
Data point term sent to Coder	System	05 Mar 2021 23:58:35
User entered 'COUGH'	(b) (4), (b) (6)	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:29
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:08:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:58:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:31
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:08:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:58:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:32
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:08:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:08:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 23:58:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:34
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '09 Oct 2020'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:35
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:37
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:58:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 23:58:29
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:58:29
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 23:58:29
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:58:02
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 23:58:02
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:40
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:41
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Grade 1/Mild (Grade 1/Mild)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:03:43
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:15
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:16
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:31
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:33
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:34
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:36
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:37
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:39
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:40
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:42
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:43
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).		16 Mar 2021 21:04:16
Query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' answered with 'UPDATED' (Site from DM).		15 Mar 2021 13:38:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:38:20
User opened query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).		15 Mar 2021 11:59:24
User entered 'Not Applicable (NOT APPLICABLE)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:45
DataPoint Verified.		29 Apr 2021 15:33:30
DataPoint Un-verified.		27 Apr 2021 17:58:36
User entered 'Not Related (NOT RELATED)'		27 Apr 2021 17:58:36
reason for change: Data Entry Error		
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Not Applicable (NOT APPLICABLE)'		06 Mar 2021 00:09:36
reason for change: Data Entry Error		
User entered 'Not Related (NOT RELATED)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:46
DataPoint Verified.		29 Apr 2021 15:33:32
DataPoint Un-verified.		27 Apr 2021 17:58:36
User entered 'None (NONE)' reason for change: Data Entry Error		27 Apr 2021 17:58:36
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Not Applicable (NOT APPLICABLE)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:47
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'I'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:49
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:51
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:52
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:54
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:04:56
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 23:58:02

US3092047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 00:08:41

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:05
DataPoint Verified.		22 Mar 2021 21:52:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (b) (4)	06 Mar 2021 00:01:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (b) (4)	06 Mar 2021 00:01:10
Data point term sent to Coder	System	06 Mar 2021 00:00:37
User entered 'BODY ACHES'	(b) (4), (b) (6)	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:07
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:09:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:09:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:09:16
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:00:05
User entered empty.	(b) (4), (b) (6)	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:08
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:09:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:09:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:09:16
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:00:05
User entered empty.	(b) (4), (b) (6)	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:10
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:09:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Mar 2021 00:09:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 00:09:16
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Mar 2021 00:00:05
User entered empty.	(b) (4), (b) (6)	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:12
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '09 Oct 2020'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:05:14
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:33
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:34
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '09 Nov 2020'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:36
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:38
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Grade 1/Mild (Grade 1/Mild)'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:40
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'No (N)'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:41
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:43
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:44
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:46
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:47
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:49
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:51
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:53
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:54
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:56
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:58
DataPoint Verified.		22 Mar 2021 21:52:20
User closed query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).		16 Mar 2021 21:04:24
Query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:38:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:38:45
User opened query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).		15 Mar 2021 11:59:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:07:59
DataPoint Verified.		29 Apr 2021 15:34:26
DataPoint Un-verified.		27 Apr 2021 17:53:28
User entered 'Not Related (NOT RELATED)'		27 Apr 2021 17:53:28
reason for change: Data Entry Error		22 Mar 2021 21:52:20
DataPoint Verified.		06 Mar 2021 00:00:05
User entered 'Not Applicable (NOT APPLICABLE)'		

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:01
DataPoint Verified.		29 Apr 2021 15:34:27
DataPoint Un-verified.		27 Apr 2021 17:53:28
User entered 'None (NONE)' reason for change: Data Entry Error		27 Apr 2021 17:53:28
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Not Applicable (NOT APPLICABLE)'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:14
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'I'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:22
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:23
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '0'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:25
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:27
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 16:08:29
DataPoint Verified.		22 Mar 2021 21:52:20
User entered empty.		06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 00:00:05

US3092047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Mar 2021 00:09:16

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
Reviewed for Safety.		17 Mar 2021 12:35:13
User entered 'USA-US086-2021-mRNA-1273-P301000013'		17 Mar 2021 12:35:08
User entered 'New'		17 Mar 2021 12:35:08

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this event as there is no ongoing MH condition of this condition or previous recorded AE. Either provide a baseline condition in MH ecrf or remove "exacerbation" in the term. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:05:05
Query 'Per DM CLR: Please review this event as there is no ongoing MH condition of this condition or previous recorded AE. Either provide a baseline condition in MH ecrf or remove "exacerbation" in the term. Else, provide clarification.' answered with 'Updated AE log with current information pending requested medical records.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:53:31
User opened query 'Per DM CLR: Please review this event as there is no ongoing MH condition of this condition or previous recorded AE. Either provide a baseline condition in MH ecrf or remove "exacerbation" in the term. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:39:18
User closed query 'PV Query: Does the subject have a history of COPD? If yes, please add to Medical History. If this is a new onset of COPD, please consider revising event term' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:53:54
Query 'PV Query: Does the subject have a history of COPD? If yes, please add to Medical History. If this is a new onset of COPD, please consider revising event term' answered with 'Yes' (Site from Safety).	Valentine Ebuh (b) (4)	26 Mar 2021 14:21:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 14:20:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 14:20:48
Data point term sent to Coder	System	26 Mar 2021 14:20:18
DataPoint Un-verified.	Valentine Ebuh (b) (4)	26 Mar 2021 14:19:22
Coding entries removed.	Valentine Ebuh (b) (4)	26 Mar 2021 14:19:22
User entered 'COPD EXACERBATION' reason for change: Data Entry Error	Valentine Ebuh (b) (4)	26 Mar 2021 14:19:22

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Audit	User	Time (GMT)
User opened query 'PV Query: Does the subject have a history of COPD? If yes, please add to Medical History. If this is a new onset of COPD, please consider revising event term' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:22:53
		22 Mar 2021 21:52:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (b) (4)	17 Mar 2021 11:57:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (b) (4)	17 Mar 2021 11:57:42
Data point term sent to Coder	System	16 Mar 2021 22:58:44
User entered 'SUSPECTED COPD EXACERBATION'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '14 Mar 2021'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:58:00

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Marissa Cervenka (b) (4)	26 Mar 2021 15:05:11
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	26 Mar 2021 15:05:11
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	26 Mar 2021 15:05:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	26 Mar 2021 15:05:11
DataPoint Un-verified.	Marissa Cervenka (b) (4)	26 Mar 2021 15:05:11
User entered '18 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	26 Mar 2021 15:05:11
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	26 Mar 2021 14:54:51
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	(b) (4)	
	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:58:00

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Apr 2021 00:51:51
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Apr 2021 00:49:13
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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Form: Adverse Events (7)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	25 Apr 2021 00:51:51
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	25 Apr 2021 00:51:51
User entered '1' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Apr 2021 00:51:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	25 Apr 2021 00:49:13
User entered '0' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Apr 2021 00:49:13
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 01:44:38
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission date is entered. Discharge date is unknown at this time. Remaining queries will be left open until the data can be updated.' (Site from System).	Marissa Cervenka (b) (4)	23 Mar 2021 23:13:22
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 21:53:39
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Mar 2021 22:58:00
User entered '1'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 15:19:56
DataPoint Verified.		22 Mar 2021 21:52:20
User entered '14 Mar 2021'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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Form: Adverse Events (7)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 20:54:38
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Faxed and emailed 27APR2021' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:58:44
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:54:01
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).		26 Mar 2021 14:52:47
DataPoint Un-verified.		26 Mar 2021 14:52:37
User entered '18 Mar 2021' reason for change: Data Entry Error		26 Mar 2021 14:52:37
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		25 Mar 2021 13:23:22
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:22:14
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	26 Mar 2021 14:53:17
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		26 Mar 2021 14:53:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:53:17
DataPoint Un-verified.		22 Mar 2021 21:53:41
DataPoint Verified.		22 Mar 2021 21:52:20
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	16 Mar 2021 22:58:00
User entered 'Unknown (UNK)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Apr 2021 00:47:27
User entered '1' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Apr 2021 00:47:27
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Apr 2021 00:46:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Mar 2021 14:54:04
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 21:53:46
DataPoint Verified.		22 Mar 2021 21:52:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Mar 2021 22:58:00
User entered '0'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this VERBATIM AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 07:53:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this VERBATIM AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'removed check and will enter once medical records are received' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	25 Apr 2021 00:48:34
User entered '0' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	25 Apr 2021 00:46:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this VERBATIM AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:39:53
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:54:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:54:38
DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 14:54:04
User entered '1' reason for change: Data Entry Error		26 Mar 2021 14:54:04

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:22:35
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:54:06
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'DONE' (Site from Safety).	Marissa Cervenka (b) (4)	26 Mar 2021 15:05:26
DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 14:54:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:54:51
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		25 Mar 2021 13:21:55
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		16 Mar 2021 22:58:00

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 21:52:20
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	16 Mar 2021 22:58:00

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The records we received were for a hospitalization on 04Apr-08Apr for worsening dyspnea and chronic left leg pain (which is not reported in EDC). Please confirm if this hospitalization event should be reported in the EDC. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:29:14
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		03 May 2021 12:29:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).		03 May 2021 12:28:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		27 Apr 2021 13:01:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No COVID-19 testing was performed during hospital admission. ' (Site from Safety).		26 Apr 2021 19:45:29
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		07 Apr 2021 20:40:20

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was reported that the subject has a history of COPD. Please add COPD to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:47:37
Query 'PV Query: It was reported that the subject has a history of COPD. Please add COPD to medical history eCRF.' answered with 'Per subject, subject was diagnosed with COPD in January of 2021. This has been recorded as an AE with the current information pending requested medical records.' (Site from Safety).		06 Apr 2021 14:55:01
User opened query 'PV Query: It was reported that the subject has a history of COPD. Please add COPD to medical history eCRF.' (Site from Safety).		05 Apr 2021 13:37:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		25 Mar 2021 13:21:42
DataPoint Verified.		22 Mar 2021 21:52:20
User entered 'SUBJECT WAS SCHEDULED FOR AN APPOINTMENT ON 15-MAR-2021.SHE CALLED AND STATED THAT SHE MISSED THE APPOINTMENT BECAUSE SHE HOSPITALIZED ON 14-MAR-2021 DUE TO COPD.NO OTHER INFORMATION WAS PROVIDED. SUBJECT HAS BEEN CONTACTED FOR ADDITIONAL INFORMATION BUT SITE HAS NOT BEEN ABLE TO SPEAK WITH HER. SAE WILL BE UPDATED WHEN INFORMATION IS AVAILABLE'	Marissa Cervenka (b) (4)	16 Mar 2021 22:58:00

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 22:58:00

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 22:58:00

US3092047

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 22:58:00

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (b) (4)	06 Apr 2021 14:49:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (b) (4)	06 Apr 2021 14:49:50
Data point term sent to Coder	System	06 Apr 2021 14:48:36
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	07 Apr 2021 14:32:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Apr 2021 14:48:16
User entered 'UN Jan 2021' (non-conformant).	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 23:50:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 14:48:16
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Vicki Martinez (b) (4)	12 Apr 2021 23:50:10
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 14:48:16

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (b) (4)	24 Apr 2021 02:59:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (b) (4)	24 Apr 2021 02:59:23
Data point term sent to Coder	System	24 Apr 2021 02:58:48
User entered 'HEADACHE'	Vicki Martinez (b) (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 17:25:54
User entered '13 Aug 2020'	Vicki Martinez (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per MM: As this event is captured as a solicited adverse reaction, please review and confirm the relationship to IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 08:12:05
Query 'Per MM: As this event is captured as a solicited adverse reaction, please review and confirm the relationship to IP and update, as appropriate. ' answered with 'UPDATED' (Site from DM).		27 Apr 2021 17:26:22
User entered 'Related (RELATED)' reason for change: Data Entry Error		27 Apr 2021 17:25:54
User opened query 'Per MM: As this event is captured as a solicited adverse reaction, please review and confirm the relationship to IP and update, as appropriate. ' (Site from DM).		27 Apr 2021 00:08:57
User entered 'Not Related (NOT RELATED)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[None](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Apr 2021 02:58:09

US3092047

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:06:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Apr 2021 02:58:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:06:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:28:51
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:50:27

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Mar 2021 00:04:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Mar 2021 00:04:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Mar 2021 00:03:42 06 Mar 2021 00:02:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:31:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:31:20
Data point term sent to Coder	System	17 Aug 2020 19:52:07
User entered 'NOVOLOG INSULIN'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'DIABETES' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:02:39
User entered 'DIABETER'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User closed query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 11:00:14
Query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:19:48
Signature has been broken.	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:19:21
User entered 'UNK' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:19:21
User opened query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you ' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 05:47:33
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	07 Mar 2021 18:18:55
User entered 'UNKOWN'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Other (OTHER)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'UNKOWN'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'unknown (UNKNOWN)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'I'	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:51:26

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Aug 2020 06:46:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 06:46:20
Data point term sent to Coder	System	17 Aug 2020 19:53:15
User entered 'LANTUS INSULIN'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'DIABETES'	(b) (4) Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User closed query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:54:13
Query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4)	12 Apr 2021 04:37:57
Signature has been broken.	(b) (4)	
User entered 'UNK' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	12 Apr 2021 04:37:48
User opened query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	11 Apr 2021 05:38:28
User entered 'UNKNOWN'	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Other (OTHER)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'UNKNOWN'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'unknown (UNKNOWN)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'I'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:52:46
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:52:46

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 19:55:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 19:55:11
Data point term sent to Coder	System	17 Aug 2020 19:54:16
User entered 'ALBUTEROL'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'ASTHMA'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered '90' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:03:49
User entered 'UNKOWN'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:03:49
User entered 'Other (OTHER)'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:03:49
User entered 'UNKOWN'	Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'as needed (PRN)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'I'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Shraddha Dubal (b) (4)	17 Aug 2020 19:53:38
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:53:38

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Nov 2020 13:54:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 13:54:42
Data point term sent to Coder	System	16 Nov 2020 13:53:41
User entered 'Flu Shot'	Catina Adams (b) (4) (b) (4)	16 Nov 2020 13:53:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Flu Prevention'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User closed query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:54:27
Query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4)	12 Apr 2021 04:40:18
Signature has been broken.	(b) (4)	
User entered 'UNK' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	12 Apr 2021 04:40:06
User opened query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	11 Apr 2021 05:38:18
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 22:08:12
	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'mL (mL)'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'other (OTHER)'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Once a year'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Catina Adams (b) (4) (b) (4)	16 Nov 2020 13:53:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '19 Oct 2020'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '19 Oct 2020'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	16 Nov 2020 13:53:09
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:53:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:53:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:53:09

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Nov 2020 15:22:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:22:43
Data point term sent to Coder	System	16 Nov 2020 15:22:07
User entered 'Tylenol'	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Yes (Y)'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

Indication

Audit	User	Time (GMT)
User closed query 'Per CDM. DM CLR re-query: Response "will update ae. there are some listed on source" is noted. Please update the AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:21:18
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
Query 'Per CDM. DM CLR re-query: Response "will update ae. there are some listed on source" is noted. Please update the AE page as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:05:20
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:02:56
User opened query 'Per CDM. DM CLR re-query: Response "will update ae. there are some listed on source" is noted. Please update the AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:02:54
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'will update ae. there are some listed on source ' (Site from DM).	destiny robinson (b) (4) (b) (4)	02 Feb 2021 20:29:16
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:32:58
User entered 'Chest Pain'	Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'UNK'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'mg (mg)'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'unknown (UNKNOWN)'	(b) (4) Catina Adams (b) (4) (b) (4)	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'Oral (ORAL)'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered empty.	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '10 Aug 2020'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '0'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered '13 Aug 2020'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
	(b) (4)	
User entered 'No (N)'	Catina Adams (b) (4)	16 Nov 2020 15:21:49
	(b) (4)	

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:21:49

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	30 Apr 2021 22:15:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	30 Apr 2021 22:15:08
Data point term sent to Coder	System	30 Apr 2021 22:14:20
Coding entries removed.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	14 Apr 2021 00:56:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	06 Apr 2021 14:59:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	06 Apr 2021 14:59:56
Data point term sent to Coder	System	06 Apr 2021 14:58:56
User entered 'ROBAXIN'	(b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered 'CHRONIC LOW BACK PAIN' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'COPD EXACERBATION'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered '750' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User closed query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 08:41:41
Query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:41:55
User entered 'UNK' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:41:46
User opened query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 05:37:47
User entered 'UNKNOWN'	(b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered 'mg (mg)' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered empty; reason for change Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered 'as needed (PRN)' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 22:14:05
User entered '13 Mar 2021' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM Re-query: Per response please update this field once the data is available.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 08:39:27
Query 'Per DM Re-query: Per response please update this field once the data is available.' answered with 'Confirmed per source' (Site from DM).		30 Apr 2021 22:14:33
Signature has been broken.		30 Apr 2021 22:14:05
User entered 'Yes (Y)' reason for change: Data Entry Error		30 Apr 2021 22:14:05
User opened query 'Per DM Re-query: Per response please update this field once the data is available.' (Site from DM).		15 Apr 2021 14:16:27
User closed query 'Data is required. Please complete.' (Site from System).		15 Apr 2021 14:14:22
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Query 'Data is required. Please complete.' answered with 'CANNOT ANSWER UNTIL THE PENDING REQUESTED MEDICAL RECORDS ARE RECEIVED' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:59:29
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 14:58:41
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 22:14:05
User entered '2'	System	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 22:14:05
User entered '1'	System	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 22:14:05
User entered '804 (804)'	System	06 Apr 2021 14:58:41

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: TORASEMIDE, PRODUCTSYNONYM: TORSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (b) (4)	06 Apr 2021 15:02:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	06 Apr 2021 15:02:56
Data point term sent to Coder	System	06 Apr 2021 15:01:59
User entered 'TORSEMIDE'	(b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'COPD EXARCEBATION'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User closed query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 08:41:47
Query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:48:12
User entered 'UNK' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 04:47:59
User opened query 'Per CDM: Please provide the numerical value in the dose field. If the dose is unknown, please record "UNK" per CCGs page 53. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 05:37:54
User entered 'UNKNOWN'	(b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered '13 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM Re-query: per response please update this field once the results are available.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:14:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 14:13:31
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Query 'Data is required. Please complete.' answered with 'CANNOT ANSWER AT THIS TIME UNTIL PENDING REQUESTED MEDICAL RECORDS ARE RECEIVED.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:04:13
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 15:01:56
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 15:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	24 Apr 2021 03:03:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (b) (4)	24 Apr 2021 03:03:14
Data point term sent to Coder	System	24 Apr 2021 03:02:49
User entered 'TYLENOL'	Vicki Martinez (b) (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Apr 2021 03:02:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Apr 2021 03:02:02
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:02:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Apr 2021 03:01:56
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:06:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Apr 2021 03:01:56

US3092047

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:06:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:18:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Mar 2021 00:01:59

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'USA-US086-2021-MRNA-1273-P301000013'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Valentine'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Ebuh'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered '2701 S Hampton Road, Suite 250'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Dallas'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'TX'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered (b) (6)	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:19:41
Signature has been broken.		08 Apr 2021 15:19:41
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 15:19:41
DataPoint Un-verified.		08 Apr 2021 15:18:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered (b) (6)	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:50:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered 'US'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 12:25:35
User entered '2'	System	29 Mar 2021 16:54:23
User entered '1'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'USA-US086-2021-MRNA-1273-P301000013'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Valentine'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Ebuh'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered '2701 S Hampton Road, Suite 250'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Dallas'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'TX'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered (b) (6)	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:19:41
Signature has been broken.		08 Apr 2021 15:19:41
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 15:19:41
DataPoint Un-verified.		08 Apr 2021 15:18:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered (b) (6)	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:50:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered 'US'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 12:25:35
User entered '2'	System	29 Mar 2021 16:54:23
User entered '1'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered '17/Mar/2021 12:35'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:06:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:50:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered 'I'		17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'USA-US086-2021-MRNA-1273-P301000013'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Valentine'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Ebuh'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered '2701 S Hampton Road, Suite 250'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Dallas'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'TX'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered (b) (6)	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:19:41
Signature has been broken.		08 Apr 2021 15:19:41
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 15:19:41
DataPoint Un-verified.		08 Apr 2021 15:18:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered (b) (6)	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:50:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered 'US'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 12:25:35
User entered '2'	System	29 Mar 2021 16:54:23
User entered '1'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:39
User entered '29/Mar/2021 12:54'	(b) (4) System	29 Mar 2021 16:54:23

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:06:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 12:25:21
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:32:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:54:23

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'USA-US086-2021-MRNA-1273-P301000013'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
User entered 'Yes (Y)'	System	25 Apr 2021 00:51:51
Un-reviewed for Safety.	System	25 Apr 2021 00:49:13
DataPoint Un-verified.	System	25 Apr 2021 00:49:13
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered 'No (N)'	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Yes (Y)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'No (N)'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Valentine'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Ebuh'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered '2701 S Hampton Road, Suite 250'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'Dallas'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered 'TX'	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:21
Signature has been broken.	System	25 Apr 2021 00:49:13
User entered (b) (6)	System	25 Apr 2021 00:49:13
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:56:17
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:19:41
Signature has been broken.		08 Apr 2021 15:19:41
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 15:19:41
DataPoint Un-verified.		08 Apr 2021 15:18:50
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
Reviewed for Safety.		17 Mar 2021 12:35:26
User entered (b) (6)	System	17 Mar 2021 12:35:08

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:50:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:51:31
User entered 'US'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:06:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 12:25:35
User entered '2'	System	29 Mar 2021 16:54:23
User entered '1'	System	17 Mar 2021 12:35:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered '26/Apr/2021 08:25'	(b) (4) System	26 Apr 2021 12:25:35

US3092047

Folder: SAE USA-US086-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:06:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:25:35